PORTABLE ELECTROSTIMULATION EQUIPMENT INSTRUCTIONS FOR USE

“Stim Care”

Illustrative picture

ANVISA NOTIFICATION No. 80212480027

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CONTENTS

1 PRESENTATION

1.1 DEAR CUSTOMER

Congratulations!!! You now have high-tech equipment of exceptional quality that, combined with your knowledge, will produce excellent results in your treatments.
However, in order to explore the most of the equipment's features, ensuring your and that of your patient's safety, it is imperative that you read this instructions for use and correctly follow its instructions. Thus, you will play the role of a professional with a high standard of service.
We, at HTM Eletrônica, are ready to clarify any doubts about the equipment's operation and also listen to your opinion and suggestions about it.

1.2 INSTRUCTIONS FOR USE

This instructions for use describes the entire process of installation, assembly, operation and technical characteristics of the portable electrostimulator **Stim** Care**,** in addition to presenting considerations about TENS, FES, High Force, Russian, Lipolysis, MENS, Galvanic, Microgalvanic currents, with regard to waveforms, indications, contraindications, electrode placement, etc.

☑ Check the correct version of the instructions for use with the equipment purchased;

☑ To request the equipment's instructions for use in printed format, access our website: www.htmeletronica.com.br or contact us by phone (19) 3808-7741.

This instructions for use contains the information necessary for the correct use of the **Stim** Care *portable electrostimulator equipment. It was prepared by trained professionals with the necessary technical qualifications for this type of literature.*

1.3 ABOUT THE Stim Care EQUIPMENT

Stim Care is the portable electrostimulator equipment developed to add the main treatments of electrostimulation, having a wide range of available currents. Its operation is practical and objective. It is characterized by having the following advantages:

☑ It has a revolutionary design, which combines beauty and practicality in operation, in addition to having portability as a characteristic;

☑ Capable of delivering currents of up to 100 mA under load of 1000 ohms on the output channels simultaneously, which also allows stimulation in large areas;

☑ It is developed with the highest digital technology, obtaining a high performance;

☑ Portable, with stainless steel clip to fix the equipment to the strap;

☑ Microcontroller with digital parameter controls;

☑ It can be powered through the power supply that comes with the equipment or 9Vdc battery;

☑ It has an internal battery charger circuit;

☑ It does not need to select working voltage (1 27 V~ or 220V~) for the source, as it works at any voltage within the range of 100V~ to 2 4 0V~;

☑ Equipment designed to meet the needs regarding therapy for neuromuscular stimulation, meeting the General standard NBR IEC 60601-1, Collateral standards NBR IEC 60601-1-2 and NBR IEC 60601-1-6 and the Particular standard NBR IEC 60601-2-10, all required for INMETRO compliance certification.

1.4 ESSENTIAL PERFORMANCE

It is understood as essential performance of the Stim Care equipment for the supply of excitomotor currents for aesthetic and physical therapy purposes within the characteristics and accuracy stated in item 12 - “Technical Specifications” of these instructions for use. Also, all equipment functions were tested in accordance with the immunity requirements of the NBR IEC 60601-1-2 standard: Collateral Standard: Electromagnetic Compatibility - Prescriptions and Tests.

2 TECHNICAL CARE

2.1 DESCRIPTION OF SYMBOLOGIES USED IN THIS INSTRUCTIONS FOR USE

Symbol	Description
	General warning symbol: means that there is a danger.
	General Prohibition Symbol: It means that the user must not perform a certain action.
	General mandatory action symbol: means that the user must perform a certain action.

2.2 TECHNICAL CARE

☑ Before turning on the equipment, make sure that you are turning it on according to the technical specifications located on the equipment label or in item 12 - Technical Specifications of this instructions for use;

☑ The **Stim** Care equipment, as well as its accessories, must not be serviced or maintained during use on a patient;

☑ A patient using an implanted electronic device (eg cardiac pacemaker) should not be subjected to pacing unless an expert medical opinion has been previously obtained;

☑ Simultaneous application to a patient of shortwave equipment, microwaves or high frequency surgical equipment with the stimulator may result in burns at the application site of the stimulator electrodes and possible damage to the equipment;

☑ The operation of shortwave or microwave equipment close to the equipment may produce instability in its output currents;

☑ The application of electrodes close to the chest may increase the risk of cardiac fibrillation;

☑ Stimulation should not be applied along or across the head, directly over the eyes, covering the mouth, in front of the neck (especially the carotid sinus), or from electrodes located on the chest and upper back or across to the heart unless a medical opinion has been obtained previously;

☑ Do not open the equipment under any circumstances, as, in addition to voiding the warranty, you will be putting your safety at risk and may damage expensive components. Any defect contact HTM Eletrônica, which will inform the nearest Authorized HTM Eletrônica Technical Assistance;

☑ Do not insert objects into the holes in the equipment and do not place containers with liquids on the equipment;

☑ Never disconnect the plug from the socket by pulling on the power cord. Also, to increase the life of the application cables, do not disconnect them from the equipment or electrodes by pulling on the wires;

☑ Do not use the equipment stacked or adjacent to other equipment;

☑ Constantly inspect the power cable and application cables, especially close to the connectors, checking for the presence of cuts in their insulation. Noticing any problem, follow the procedures described for equipment maintenance;

☑ Special attention is recommended to the user when the current density for any electrode exceeds 2 mA rms/cm². Note that the smaller the electrode area, the greater the current density (mA /cm²).

WARNING: No modifications to this equipment are permitted.

2.3 CLEANING CARE

☑ After using the silicone electrodes and the tips and pen electrodes, wash them with running water and neutral soap;

☑ After using the electrodes with a vegetable sponge, wash them with running water;

☑ Use a dry cloth to clean the equipment. By doing so you will be conserving your equipment.

Do not use the accessories without proper hygiene!

2.4 STORAGE PRECAUTIONS

☑ Do not store the equipment in damp places or places subject to condensation;

☑ Do not store the equipment in an environment with a temperature above 60ºC or below -20ºC;

☑ Do not expose the equipment to direct sunlight, rain or excessive humidity

2.5 TRANSPORT PRECAUTIONS

☑ If you need to transport the equipment, use the same packaging process used by HTM Eletrônica. By doing so, you will be guaranteeing the integrity of the equipment. For this, it is advisable to keep the equipment packaging;

☑ When shipping equipment between locations, we recommend using carriers for the following models*:

- Beauty Shape Duo;
- Light Pulse;
- Pluria (if shipped with rack);
- Ácrus.
- Ultrafocus (if shipped with rack);
- Vibria Maxx (if shipped with rack);
- Límine (if shipped with rack);

NOTE!

* These models mentioned are some of the models that were in our portfolio at the time of publication of these instructions for use. For an updated list of equipment that we recommend using shipping carriers, please contact HTM ELETRÔNICA. Other equipment can also be transported by the Post Office.

It is important to emphasize the use of packaging materials in all cases of transporting the equipment.

3 Stim Care EQUIPMENT ACCESSORIES

3.1 ACCESSORIES THAT COME WITH THE EQUIPMENT Stim Care

☑ 02 Cables for application with banana pin;

Code HTM 006937: White cable banana pin emb. 1un
Code HTM 006938: Black cable banana pin emb. 1un

☑ 01 Bivolt power supply;

Code HTM 006587: HTM Portable Stimulator Power Supply

☑ 04 Electrodes 7cm x 5cm.

Code HTM 003130 Silicone Electrode 7x5cm in pack. 4un

☑ 02 large elastic straps;

Code HTM 003124: Elastic Strap Large Pc. 2 one

☑ 01 Sachet of Conductive Gel ANVISA Registration: No. 80122200001 or nº10340440046;

Code HTM 00 7300 : Conductive Gel Sache 100G (Value > 6 months)

3.2 OPTIONAL Stim Care EQUIPMENT ACCESSORIES (DOES NOT COME WITH THE EQUIPMENT)

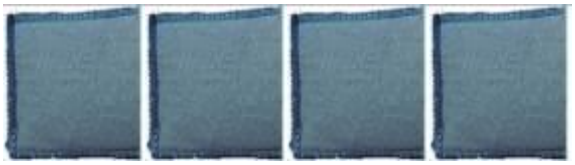
☑ 01 Kit for electrolipolysis with needles;

Code HTM 00 6864: Electrolipolysis kit est. portable emb. 1un

☑ 01 Stim care facial kit;

Code HTM 008407: Stim Care Facial Kit emb. 1un

☑ 04 Aluminum electrodes with vegetable sponge 13cm x 10 cm;



Code HTM 003131: Sponge Electrode 13X10cm in pack. 2un

☑ 01 Aluminum electrode with vegetable sponge 7.5cm x 6.5cm;

Code HTM 003132: Sponge Electrode 7.5X6.5cm Pc. 2un

☑ 04 Electrolipolysis electrodes;

Code HTM 003133: Silicone Electrode 10X2 cm in pack. 4un

☑ 04 Silicone electrodes 1cm x 3cm;

Code HTM 003127: Silicone Electrode 1X3 cm in pack. 4un

☑ 04 Electrodes 5cm x 5cm;

Code HTM 003129: Silicone Electrode 5X5 cm in pack. 4un

☑ 01 large roll type tip;

Code HTM 003136: Facial Roller Tip in pack. 1un

☑ 01 Kit of needles for microgalvanopuncture;

Code HTM 002715: Needle for microgalvanopuncture emb. 20un

☑ 02 Cables for application with alligator clip.

Code HTM 006925: White cable with alligator clip emb. 1un
Code HTM 006936: Black handle with alligator clip emb. 1un

☑ 02 small elastic straps;

Code HTM 003122: Small Elastic Strap pack 2un

NOTE!

Illustrative images.

4 INSTALLATION

4.1 Stim Care EQUIPMENT INSTALLATION

1) Connect the plug of the external power supply to the equipment's power input and to the mains socket, make sure that the mains voltage value is within the range of 100V~ to 240V~.

☑ The equipment does not need to be connected with a line filter, as it has an internal filter;

☑ The use of precarious electrical installations can cause safety risks;

☑ It is recommended that the equipment be installed in places that work in accordance with the NBR 13534 standard, which concerns clinical and hospital facilities;

☑ Avoid places subject to vibrations;

☑ Avoid humid, hot or dusty places;

☑ Install the equipment on a firm and horizontal surface, in a place with good ventilation;

☑ In the case of a built-in cabinet, make sure that there is no impediment to the free circulation of air at the rear of the equipment;

☑ Do not rest on rugs, pillows or other soft surfaces that obstruct ventilation;

☑ Position the power cable and application cables so that they are free, out of places where they can be walked on. Do not place any furniture on them;

☑ Handle the equipment and cables with care, as mechanical impacts can adversely affect their characteristics.

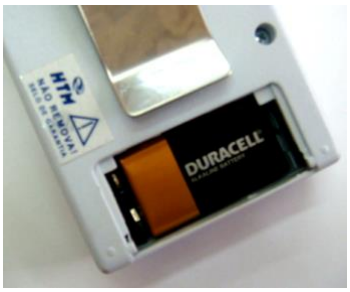
2) If you want to use the equipment with battery power, follow these steps:

- Remove the battery compartment cover. To do this, press and slide the cover off the equipment.

- Configure the type of battery that will be used according to the instructions in item 10 of the instructions for use.

☑ Incorrect battery type setting can create a risk of battery leakage or explosion. Only rechargeable batteries can be recharged.

- Insert a 9Vdc battery (alkaline or rechargeable NiMH) by connecting it to the battery terminal.



- Replace the battery compartment cover. To do this, fit the cover, tighten it and slide it towards the equipment.

Illustrative Images!

☑ Only 9Vdc alkaline battery or 9Vdc NiMH rechargeable batteries should be used.

☑ It must be checked before each use of the equipment that the battery is charged, this can be verified by connecting it to the equipment. If the battery is low, it will show the message “Connect the source” on the display. If necessary, replace or charge the battery or connect the equipment to the power supply using the power supply supplied with the equipment.

☑ The battery must be removed from the equipment if it is not used for long periods (more than one month);

☑ Ni-MH rechargeable batteries have charge for immediate use, with prolonged storage, the battery will lose its initial charge. We recommend that the battery be completely discharged on first use. Afterwards, it must be charged for a minimum of 12 hours and a maximum of 18 hours. Rechargeable batteries require regular full discharges.

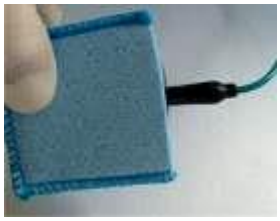
3) Connect the application cables to the equipment outlets located on the top of the **Stim** Care equipment, as well as the cable type for each available current.

4) Connect the banana pins to the electrode holes. Application cable pins must be fully inserted into the electrodes. For galvanic current connect the alligator clip to the aluminum electrodes.

Press alligator claw

Attach the clamp to the electrode

Insert the electrode into the sponge

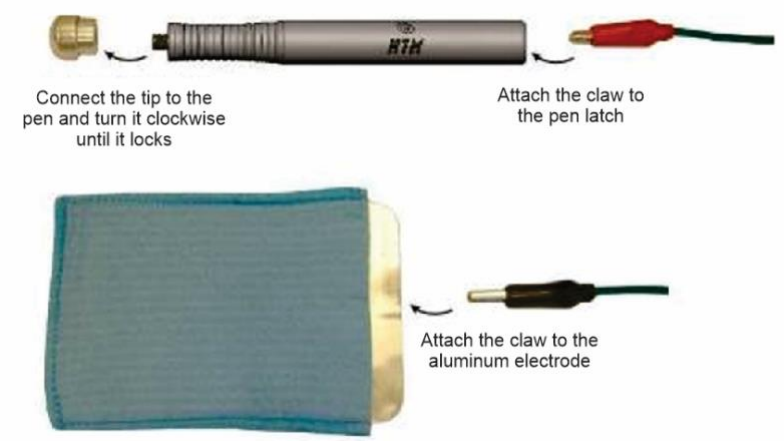


Connect the banana pin to the electrode

Press the alligator clip and attach it to the needle

Never reuse needles. The needles are for single use and must be discarded after use in a specific container (sharp material collector).

4.2 CONNECTION OF THE PEN FOR STIMULATION



4.3 ELECTROMAGNETIC INTERFERENCE

The **Stim** Care equipment does not cause significant interference with other equipment; however, it may suffer interference and have its functions altered if subjected to a strong electromagnetic field. Based on this information, we must take the following precautions:

☑ The **Stim** Care equipment must not be used too close together or stacked on top of other equipment. If this is necessary, it is recommended that the equipment be observed to verify normal operation in the configuration in which it will be used;

☑ The **Stim** Care equipment must not be physically connected near Diathermy equipment and Electric Motors;

☑ The power supply system (phases and neutral) of the **Stim** Care equipment must be separate from the system used by diathermy equipment and Electric Motors;

☑ This equipment requires special precautions regarding its ELECTROMAGNETIC COMPATIBILITY and needs to be installed and put into operation in accordance with the information on ELECTROMAGNETIC COMPATIBILITY provided in this instruction instructions for use;

☑ Portable and mobile RF equipment can affect **Stim** Care equipment;

☑ The external power supply and other accessories of the **Stim** Care equipment are approved parts and cannot be replaced by others not specified by the manufacturer, in order to avoid degradation of equipment safety;

☑ The use of power supply and/or cables other than those specified, with the exception of those sold by the equipment manufacturer as replacement parts, may result in increased emissions or decreased equipment immunity.

NOTE!

“Attention: Equipment intended for use only by trained professionals in the areas of health and beauty. This equipment may cause radio interference or may interrupt the operation of nearby equipment. It may be necessary to take mitigating measures, such as reorienting or relocating equipment or shielding the site.”

PROFILE OF THE INTENDED USER

- Professionals with training in the health or beauty area. There is no maximum user knowledge level;
- Instructions for use are available in English;
- Regarding the minimum experience level, it is necessary to read the instruction instructions for use. There is no maximum experience level;

- Slight visual imperfection for reading or vision corrected by corrective lenses, hearing impairment of up to 40% resulting in 60% of normal hearing are admissible for using the equipment;
- The user must have full cognitive functions;
- The user must have complete motor functions necessary for handling the equipment.

PATIENT POPULATION

- Patients over 12 years of age. Below this age only under medical or physical therapy prescription;
- Patients weighing more than 35 kg;
- There are no restrictions on use regarding nationality;
- Patients with preserved level of consciousness and sensitivity.

TERMS OF USE

- Professional use, not suitable for home use;
- This equipment is reusable, and has no limitations on frequency of use;
- This equipment is considered portable;
- The equipment can be used on any body region, except over the eyes, precordial region, carotid region and genital areas.

4.4 LIST OF ACCESSORIES IN COMPLIANCE WITH THE REQUIREMENTS OF NBR IEC 60601-1-2

☑ Automatic Bivolt Supply 9Vdc;

☑ Cables for application with banana pin;

☑ Cables for application with alligator clip;

☑ Cable for application with banana pin and alligator clip.

5 CONSIDERATIONS REGARDING CURRENTS

5.1 CONSIDERATIONS ABOUT LOW FREQUENCY CURRENTS

5.1.1 TENS

DEFINITION

The term TENS is an acronym for *Transcutaneous electrical nervous stimulation* which means, transcutaneous electrical nerve stimulation. It is a valuable physical resource, non - invasive, low cost, safe and used to promote the symptomatic relief of pain of different origins, both acute and chronic pain.

It is an electric current with an asymmetric and balanced biphasic waveform that can be applied for long periods as it does not present undesirable electrolytic effects.

PHYSIOLOGICAL EFFECTS

Transcutaneous electrical nerve stimulation (TENS) activates a complex neuronal network to reduce pain. The technique consists of the application of percutaneous electrodes, with the aim of stimulating the sensory nerve fibers.

- Gate theory: the excitation of large diameter myelinated fibers (A-beta afferent type) blocks the transmission of painful impulses, carried by small diameter fibers (A-delta and C afferent fibers), in the gray matter of the horn back of the spinal cord.
- Neuropharmacological theory: afferent electrical impulses trigger the release of endogenous opioids, enkephalin and endorphin, found in segmental neurons of the spinal cord and in descending pathways releasing serotonin and norepinephrine. In this way, nociceptive transmission is blocked through a postsynaptic mechanism that involves hyperpolarization of the postsynaptic membrane.

APPLICATION TECHNIQUES

The positioning of the electrodes is of fundamental importance to obtain a successful treatment. There are several ways to position the electrodes. Channel positions vary in each of the ways, but the variations are all made to get the most coverage of the pain-affected region. Among the most used ways can be mentioned:

- Unilateral: consists of placing an electrode on one side of a joint;

- Bilateral: consists of placing two electrodes from the same channel on a single side of the back, abdomen, arm, etc.;
- Crusade: consists of the use of 2 channels, arranging the electrodes in a crossed manner, obtaining a high current density in the region of pain;
- Proximal: consists of placing the electrodes on top of the lesion. This form of application is quite effective in the treatment of spinal cord and peripheral nerve injuries;
- Distal: consists of placing skin minus one electrode in the region of pain to ensure that paresthesia is perceived in the entire affected area;
- Linear: consists of placing the electrode both proximally and distally, as well as in regions with nerve ramifications related to pain;
- Alternating: consists of placing electrodes in a linear fashion, alternating channels in order to achieve a more homogeneous distribution of paresthesia in the region affected by pain;
- Myotome segmentally related: consists of placing electrodes on muscles innervated by the same medullary levels of the region affected by pain; however, keeping a certain distance from the region affected by the pain. This form of application is indicated for patients who have unbearable pain;
- Remote: consists of placing the electrodes in limited regions, whether or not they are related to the painful region. It may have a remote site located near, distal or contralateral to the painful region. In these regions, most of the time, strong stimulation is used;
- Transcranial: consists of placing electrodes in the temporal regions.

For application of this current, cables for application with banana pin in the respective colors of the desired channel must be used and the outputs identified below must be used.

5.1.2 FES

DEFINITION

The word FES corresponds to the abbreviation of the English term*, Functional electrical Stimulation* which means Stimulation Functional Electric.

FES is a form of electrotherapy capable of producing muscle contractions with functional objectives, that is, it can be applied in order to obtain a muscle contraction during a functional activity, in order to facilitate the control of movement and/or posture.

The same electrical stimulation can also be applied therapeutically for short periods, from an intensity that causes muscle contraction, without any functional movement, as a way of inducing muscle strengthening. This form of therapy is called *Neuromuscular Electrical. Stimulation (*NMES), i.e., neuromuscular electrical stimulation.

PHYSIOLOGICAL EFFECTS

Electrical stimulation has wide application in the treatment of individuals with muscle atrophy due to long immobilization time due to surgery or fractures.

The application of FES or NMES electrically stimulates the intramuscular branches of the motoneurons, which induces muscle contraction. Action potentials are generated both in the intramuscular nerve and in the cutaneous receptors, generating force directly by activating the motor axon and, indirectly, by the reflex recruitment of spinal motoneurons. Electrically induced muscle contraction is physiologically different from voluntary contraction. The main difference is in the recruitment of motor units.

In voluntary muscle contraction, the slower motor units (type I) are used for small efforts, while the faster ones (type II) are gradually recruited when there are higher levels of force production.

During electrostimulation, recruitment occurs in reverse. There is a greater recruitment of motor units, with type II being the first to be recruited, because these motor units need lower stimulation intensities, which may explain the ability of electrostimulation to produce muscle strengthening, with lower levels of intensity than those required during voluntary contraction.

Electrostimulation associated with voluntary movement causes greater recruitment of motor units, since it makes inactive motor units (type II) to be recruited more easily, which increases muscle performance causing greater strengthening in a short space of time. time.

In addition, in individuals with lesions involving upper motor neurons, such as hemiplegic and paraplegic individuals, the electrical stimulus causes muscle contraction through sensory pathways, which contribute to the normalization of basic reflex motor activities. Immediate effects include reciprocal inhibition and relaxation of spastic muscle and sensory stimulation of afferent pathways restoring blocked proprioceptive feedback and late effects, which act to stimulate neuroplasticity.

APPLICATION TECHNIQUES

The application technique varies according to the treatment objective, see the following information:

Muscle Strengthening

- When the treatment objective is to strengthen muscle fibers that have suffered atrophy due to disuse, upper motoneuron injuries, orthopedic trauma, arthritis, incomplete spinal cord injuries, etc.;
- The current intensity varies depending on several factors, but in any situation, it must generate a contraction capable of generating controlled movement.
- With pulse repetition frequency, within the range from 20 to 50 Hz, allowing contraction to occur;
- ON Cycle within the range of 4 to 6 seconds and OFF Cycle of 12 to 18 seconds, always maintaining a 1 to 3 ratio between the ON and OFF Cycle.
- The application time can vary from 30 minutes to 1 hour, with 2 applications being carried out every 24 hours.
- The placement of the electrodes must be close to the muscles to be stimulated.

Attention should be paid to the occurrence of muscle fatigue.

Neuromuscular Facilitation

It acts as an element of motor relearning increasing the awareness of movements in patients who had motor losses. Its main indications are to treat patients: hemiplegic, who had orthopedic immobilization, with head trauma, with peripheral nerve injuries, without degeneration reaction, with incomplete spinal cord trauma, etc.

- Current intensity varies depending on several factors, but it should be sufficient to start and finish the desired movement, helping the patient's voluntary movement;

- Pulse repetition frequency (Rate) within the range from 20 to 50 Hz, allowing contraction to occur;
- ON cycle and OFF cycle capable of performing the desired movement, with maximum patient participation;
- The application time can be small, however, several times a day. Advises maximum durations of 15 minutes;
- Positioning of the electrodes should be in the paretic muscles agonists of the movement to be facilitated.

There must be interaction with the patient so that he can assist in the movement programming process.

Spasticity Control

It acts in the control of spasticity, which allows the performance of functional training programs, with gains in muscle strengthening. It is indicated for the treatment of spastic hemiplegic patients.

- Low current intensity to avoid muscle fatigue;
- Pulse repetition frequency within the range from 20 to 50 Hz, allowing contraction to occur;
- High ON cycle and OFF cycle (10 seconds and 30 seconds respectively) capable of moving the entire joint and resting long enough to minimize fatigue;
- Application time of 30 minutes, every 8 hours, for 30 days;
- Positioning of the electrodes should be such as to provoke movement of the joints.

Treatment should be discontinued if a paradoxical response is observed.

Range of Motion and Contractures

Increase the execution of the joints making it as much as possible. It is indicated for patients with joint limitations and contractures.

- Current intensity varies depending on several factors, but it must be sufficient to generate a wide and uniform contraction of the muscle, in order to move the joint throughout its excursion;
- Pulse repetition frequency within the range from 20 to 50 Hz, allowing contraction to occur;
- 6 second ON cycle and 12 second OFF cycle, maintaining a 1 to 2 ratio;

- The application time varies depending on the objective. To maintain the Range of Motion, applications must be carried out for 30 to 60 minutes, to increase, from 1 to 2 hours;
- Positioning of the electrodes should be in the agonist muscles to limited movement.
- There should be precautions against excessive movement to avoid joint damage.

For application of this current, cables for application with banana pin in the respective colors of the desired channel must be used and the outputs identified below must be used.

5.1.3 ELECTROLIPOLYSIS

DEFINITION

Electrolipolysis is a technique for the treatment of localized adiposity, through the application of several pairs of acupuncture needles in the subcutaneous tissue, connected to a low frequency current.

PHYSIOLOGICAL EFFECTS

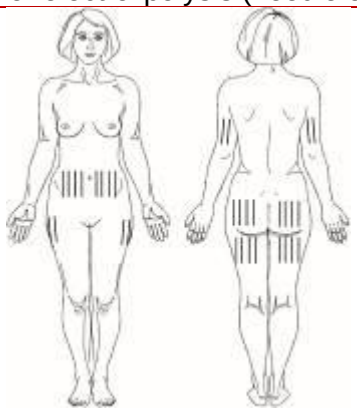
The hydro-lipolytic action of the current begins with the stimulation of the sympathetic nervous system, causing the release of adrenaline and noradrenaline hormones.

Both bind to beta-adrenergic receptors present in the cell membrane of adipocytes, causing biochemical reactions that will culminate in the activation of the hormone-sensitive enzyme triglyceride lipase, which hydrolyzes triacylglycerols. As a result, glycerol and fatty acids are released.

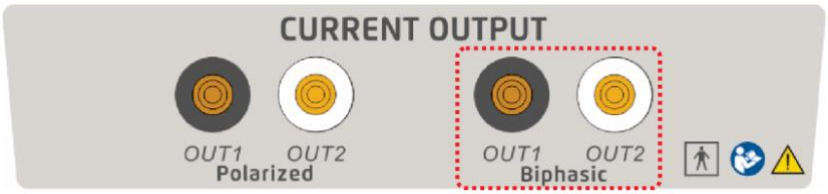
Free fatty acids are transported by albumin in plasma to cells, where they are oxidized for energy. Glycerol, in turn, is transported by the blood to the liver and can be used to form triacylglycerol.

APPLICATION TECHNIQUES

Placement of electrodes for electrolipolysis (needle electrode or carbon silicone)



To apply this current, cables for electrolipolysis with alligator clips must be used and the outputs identified below must be used. For percutaneous applications, needles for electrolipolysis should be used and for transcutaneous applications, electrodes for electrolipolysis should be used.



Never reuse needles. The needles are for single use and must be discarded after use in a specific container (sharp material collector).

5.2 CONSIDERATIONS ABOUT MEDIUM FREQUENCY CURRENTS

DEFINITION

In recent decades, neuromuscular electrical stimulation has been used in muscle strengthening. Excitomotor currents are classified according to their frequency, which means the number of oscillations of a movement in a unit of time. In this case, the unit “Hz” (cycles per second) is used. The equipment allows the use of carrier currents of 1,000 and 2,500 Hz with the possibility of modulations from 1 to 200 Hz. Thus, more recently, the use of a new nomenclature, burst modulated alternating currents, has emerged in order to characterize and differentiate them from muscle electrostimulation performed with low frequency current.

PHYSIOLOGICAL EFFECTS

Medium-frequency electric currents occupy measurements between 1,000 Hz and 100,000 Hz, and the advantages of their use are multiple, the main one being related to internal resistance, that is, the resistance that tissues offer to the conduction of electric current.

As the impedance of the human body is capacitive, and in capacitive systems, the higher the frequency, the lower the resistance present, medium frequency currents offer a pleasant sensation in the stimulus.

Currents of 1,000 Hz and 2,500 Hz are the most commonly used for muscle strengthening, both for aesthetic and rehabilitation purposes.

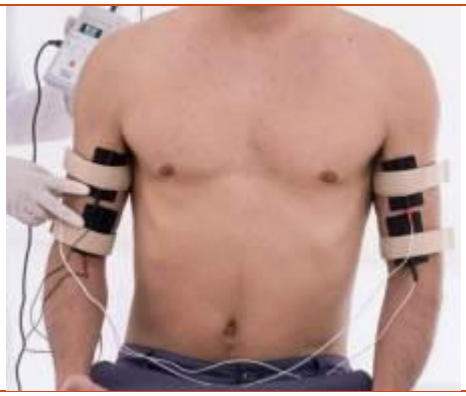
APPLICATION TECHNIQUES

High Force and Russian

There are two ways to perform electrostimulation: the bipolar technique and the motor point technique.

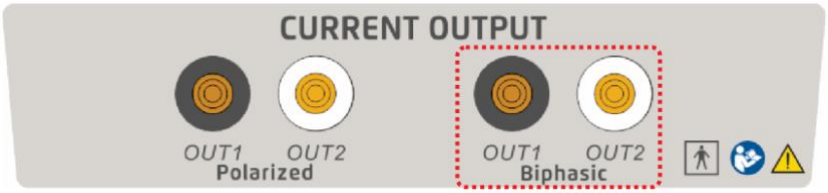
1. The bipolar technique consists of placing electrodes at both ends of a muscle, one at the origin and one at the muscle belly;
2. The motor point is where the nerve penetrates the epimysium and branches, where each nerve fiber can innervate 1 muscle fiber or even more than 150 fibers. The location of the motor point is always less sensitive, therefore, stimulation through them is better than in other areas because it allows the recruitment of a greater number of muscle fibers.

Dynamic stimulation	Fixed stimulation
	

Placement of body electrodes	
	

Voluntary muscle contraction can and should be added to electrostimulation to maximize results.

For application of these currents, cables for application with banana pin must be used and the outputs identified below must be used.



If the face kit (optional accessory) is used, the cable with alligator clip (which comes with the kit) must be used and any of the outputs identified above can be used.

5.2.1 IONIZATION

DEFINITION

Ionization, iontophoresis or descaling, is the method of transdermal administration of substances that will be used for therapeutic purposes. The basis of ion transfer success lies in the basic physical principle, like poles repel each other and opposite poles attract.

PHYSIOLOGICAL EFFECTS

The use of current or electrical potential difference provides alternatives to increase the transdermal penetration of hydrophilic and ionizable actives. The mechanisms involved in the increase in skin permeation are:

- Electrorepulsion: the interaction of the active with the electric field, generates an additional force to direct ions of similar polarity to the electrode under which they are placed;

- Electroosmosis: transdermal movement of part of the solvent together with the neutral and ionic components diluted therein;
- Increase of the intrinsic permeability of the skin by the application of electric flux.

APPLICATION TECHNIQUES

Body Ionization (Fixed Application)	Facial Ionization (Mobile App)
	

In the fixed application, the electrodes are made of aluminum, plate type, protected by a moistened sponge. The active electrode should be placed over the desired application site and the passive electrode in a nearby location. The electrodes must be equidistant from each other, that is, the distance between them must be greater than the largest dimension of the electrode, avoiding irritation and/or chemical burns.

In mobile application, the active electrode is the facial roller and the passive electrode is the aluminum electrode attached close to the treated region. The cosmetic is dripped onto the skin and the roller is slid over it to facilitate its penetration.

Descale

Technique that uses galvanic current to facilitate the removal of excess sebaceous secretion from the surface of the skin. The products perform saponification or detergent effect with the fatty acids in the sebaceous secretion, transforming them into soap. The function of the current is to facilitate the penetration of the product (the polarity of the device is the same as that of the product).

The hook pen must be wrapped with cotton and soaked in some descaling substance, without the metallic part coming into contact with the skin, so that there is no burn.

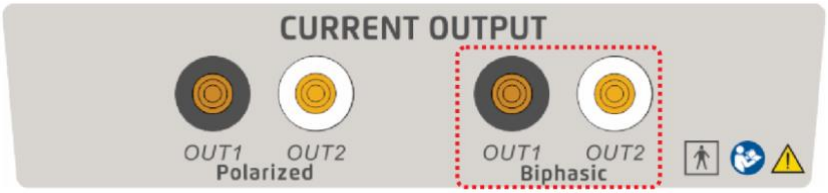
The passive electrode is the aluminum electrode, which must be placed in a region close to the treatment site.

The application time varies depending on the application mode: fixed or mobile. With fixed electrodes, the time should be shorter, as there is a greater concentration

of current in the tissues. With the mobile electrode, in addition to reducing the current concentration, the extension of the area to be treated must be taken into account.

Descale application

For application of these currents, cables for application with banana pin must be used and the outputs identified below must be used.



5.3 CONSIDERATIONS ABOUT MICROCURRENTS

5.3.1 MENS

DEFINITION

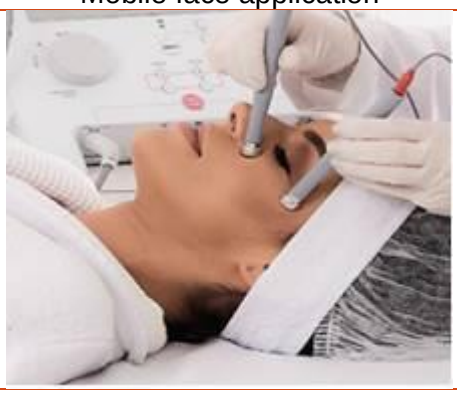
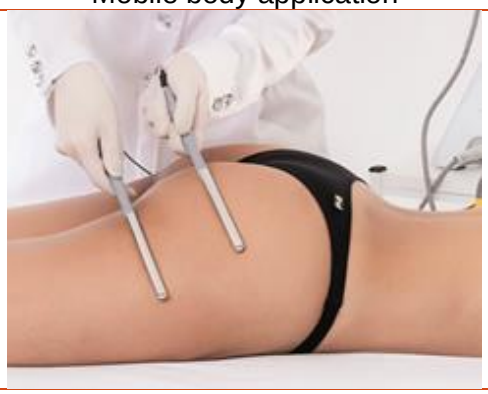
The term MENS is an acronym for Microcurrent Electrical Neuromuscular Stimulation. It is a type of electrostimulation that uses low frequency currents, with intensity in the microampere range, which can be direct or alternating current.

PHYSIOLOGICAL EFFECTS

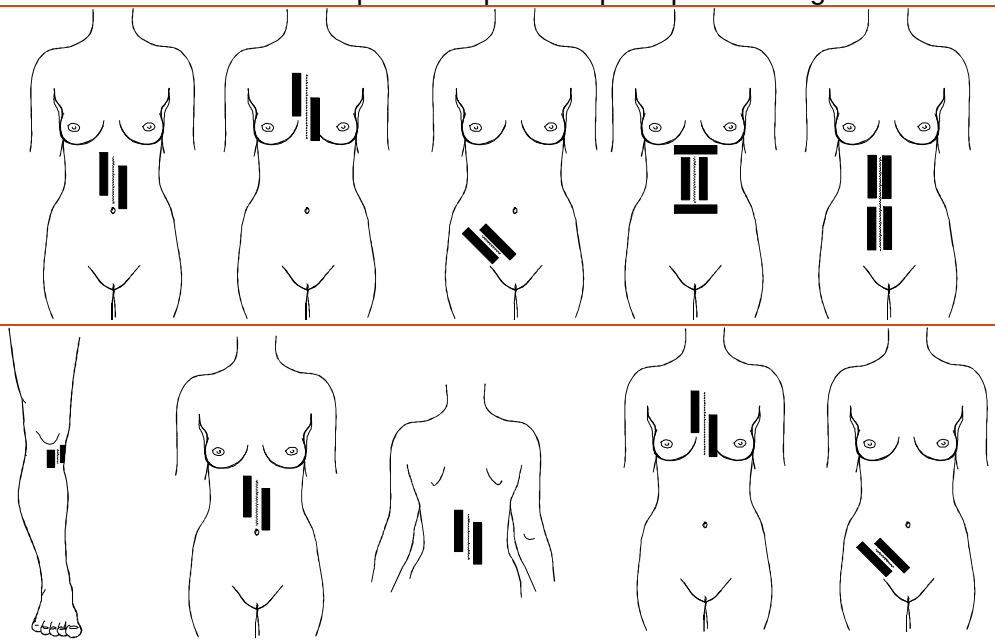
- Restoration of tissue bioelectricity: MENS works at the cellular level, creating an electrical current vehicle to compensate for the decrease in bioelectric current available to injured tissue. The application of microcurrents to an injured site can increase the flow of endogenous current. This allows the traumatized area to regain its capacitance. The resistance of this injured tissue is then reduced allowing bioelectricity to enter this area to restore homeostasis.
- Synthesis of ATP (Adenosine Triphosphate): ATP is an essential factor in the healing process. This molecule is the main source of cellular energy and largely responsible for protein synthesis and tissue regeneration, due to its

participation in all energy processes of the cell. The use of microcurrents increases ATP production by up to 500%, which consequently increases the transport of amino acids. These two factors contribute to an increase in protein synthesis. This increase results in better healing, faster recovery and minimization of pain sensation.

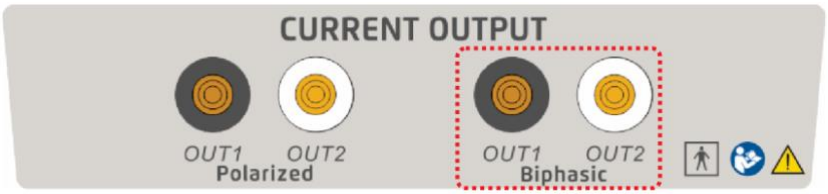
APPLICATION TECHNIQUES

Mobile face application	Mobile body application
	

Positions of electrodes placed to promote postoperative regeneration



For application of these currents, cables for application with banana pin must be used and the outputs identified below must be used.



5.3.2 MICROGALVANOPUNCTURE

DEFINITION

Microgalvanopuncture is used in the treatment of acquired linear atrophies such as striae and wrinkles, and is based on the physiological effects of direct current of intensity given in microamperage.

PHYSIOLOGICAL EFFECTS

This technique associates the intrinsic effects of the galvanic current, such as sensory stimulation, capillary hyperemia, increased circulation, area nutrition and acceleration of the healing process, with the effects of the inflammatory process.

They are induced by the puncture of the needle, which is also the means by which the current is transmitted to the skin.

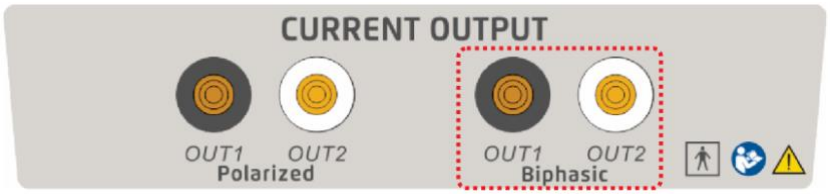
The ionic mobilization of water and blood cells and electroendosmosis, make it possible to soften dermal lesions at the negative pole, which are the basis for treatment.

APPLICATION TECHNIQUES

Negative polarity must be used on the active electrode, due to the vasodilator effect.

Facial application	Body Application
	

For application of this current, the cables for application with alligator clips must be used and the outputs identified below must be used.



Never reuse needles. The needles are for single use and must be discarded after use in a specific container (sharp material collector).

6 GENERAL INDICATIONS AND CONTRAINDICATIONS

6.1 GENERAL INDICATIONS

- ☑ Analgesia;
- ☑ Localized adiposity and cellulite;
- ☑ Muscle strengthening;
- ☑ Skin permeation of assets;
- ☑ Water retention;
- ☑ Tissue repair.

6.2 GENERAL CONTRAINDICATIONS

- ☑ Congestive heart failure;
- ☑ Absence of the skullcap;
- ☑ Craniofacial malformations;
- ☑ Shunts;
- ☑ Bypass valves;
- ☑ Ventricular catheter;
- ☑ Neural implants;
- ☑ Metal implants;
- ☑ Cochlear implants;
- ☑ Hearing aids;
- ☑ Metal fittings in the vicinity of the application;
- ☑ Renal insufficiency;
- ☑ Pacemaker wearers;
- ☑ Metal implants;

- ☑ Cardiac area;
- ☑ Peripheral vascular disease;
- ☑ Hypertension or hypotension;
- ☑ Active infection areas;
- ☑ Altered sensitivity;
- ☑ Pregnancy;
- ☑ Epilepsy;
- ☑ Phrenic nerve;
- ☑ Carotid sinus;
- ☑ Mucous membranes;
- ☑ Venous or arterial thrombus;
- ☑ Pain syndromes of unknown etiology;
- ☑ Non-consolidated fractures;
- ☑ Peripheral nerve damage;
- ☑ Over the eyeball;
- ☑ Over wounds or skin abrasions;
- ☑ Neoplasms;
- ☑ Areas treated by radiotherapy.

7 TREATMENT PROTOCOLS

7.1 TENS

Protocol	Mode	Wrist width (μs)	Frequency (Hz)	Time
Acute pain	Conventional	50 μs	100 Hz	30 min
Chronic pain	Normal	250 μs	10 Hz	30 min

7.2 FES

Protocol	Mode	Wrist width (μS)	Frequency (Hz)	Time	Rise	On	Decay	Off
Gait training	Reciprocal	250 μs	50 Hz	15 min	2	6	2	1
Control spasticity	Reciprocal	400 μs	30 Hz	20 min	2	5	2	1
Neuromuscular facilitation	Synced	400 μs	30 Hz	30 min	2	8	2	10

7.3 HIGH FORCE

Protocol	Mode	Duty cycle	Frequency (Hz)	Time	Rise	On	Decay	Off
Initial muscle conditioning	Synced	2 ms	30 Hz	20 min	2	4	1	8
Initial toning	Synced	2 ms	50 Hz	20 min	2	4	1	8
Force initial resistance	Synced	2 ms	80 Hz	20 min	1	8	1	8
Initial hypertrophy	Synced	2 ms	120 Hz	20 min	1	8	1	15

7.4 RUSSIAN

Protocol	Mode	duty cycle	Frequency (Hz)	Time	Rise	On	Decay	Off
Intermediate muscle conditioning _	Synced	50%	30 Hz	30 min	2	4	1	8
Toning intermediary	Synced	50%	50 Hz	30 min	2	4	1	8
Force resistance intermediary	Synced	50%	80 Hz	30 min	1	8	1	8
Intermediate hypertrophy	Synced	50%	120 Hz	30 min	1	8	1	15
Facial stimulation	Continuous	50%	50 Hz	20 min	-	-	-	-

7.5 LIPOLYSIS

Protocol	Wrist width (us)	Frequency (Hz)	Time
Phase 1 percutaneous electrolipolysis (lipolysis)	600 μs	5 Hz	50 min
Phase 2 percutaneous electrolipolysis (circulatory)	600 μs	10 Hz	10 min
Phase 1 transcutaneous electrolipolysis (lipolysis)	600 μs	5 Hz	50 min
Phase 1 transcutaneous electrolipolysis (lipolysis)	600 μs	10 Hz	10 min

7.6 GALVANIC

Protocol	Polarity	Time
Ionthoporation	Normal	10 min

7.7 MICROGALVANIC

Protocol	Polarity	Time
Dermopuncture	Inverted	10 min

7.8 MENS

Protocol	Mode	Frequency (Hz)	Time
Superficial tissue repair	Auto	100 Hz	20 min
Deep tissue repair	Auto	600 Hz	40 min
Burnt rehabilitation	Auto	100 Hz	40 min
Ulcer rehabilitation	Auto	150 Hz	40 min
Acne injury	Auto	200 Hz	20 min
Rejuvenation	Auto	200 Hz	20 min
Normalization	Auto	100 Hz	10 min
Nutrition	Inverted	100 Hz	10 min

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9 Stim Care EQUIPMENT CONTROLS AND INDICATIONS

9.1 Stim Care EQUIPMENT PANEL

9.1.1 DESCRIPTION OF CONTROLS AND INDICATIONS ON THE Stim Care EQUIPMENT PANEL

The item numbers below correspond to the numbers indicated on the panel above.

1 - Off key
Key that turns off the equipment;

2 - On key
Key that turns on the equipment;

3 - Graphic display
Responsible for indicating the parameters to be defined for the application of the Stim Care;

4 - Select key
Responsible for selecting the parameters to be defined for Stim Care application;

5 - Down key of the selected parameter
Responsible for the decrease to the selected parameter;

6 - Up key of the selected parameter
Responsible for adding the selected parameter;

7 - Channel 1 Intensity Up key
Responsible for increasing the intensity of channel 1;

8 - Channel 1 Intensity Down Key
Responsible for decreasing the intensity of channel 1;

9 - Channel 2 Intensity Up key
Responsible for increasing the intensity of channel 2;

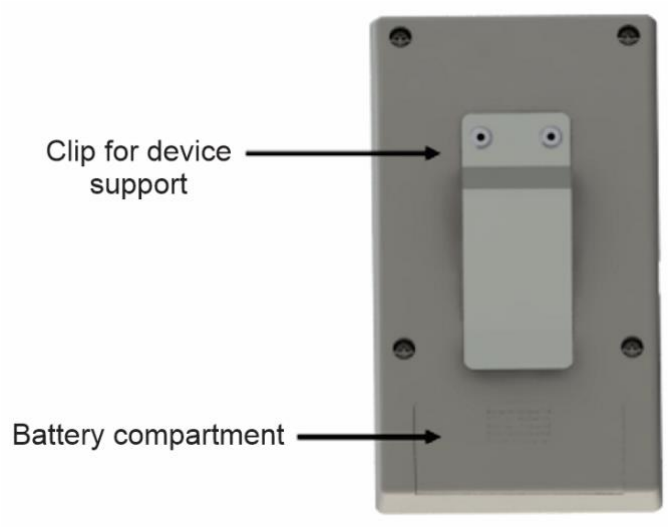
10 - Channel 2 Intensity Down Key
Responsible for decreasing the intensity of channel 2;

11 - START/STOP key
Responsible for the initialization of the application and for the interruption of the application before it closes for the programmed application time;

12 - 9Vdc Source input DC IN connector
Responsible for connecting the 9Vdc source plug;

13 - Channel output indicator light
Responsible for the channel intensity output indication.

9.2 DESCRIPTION OF THE BACK OF THE Stim Care EQUIPMENT



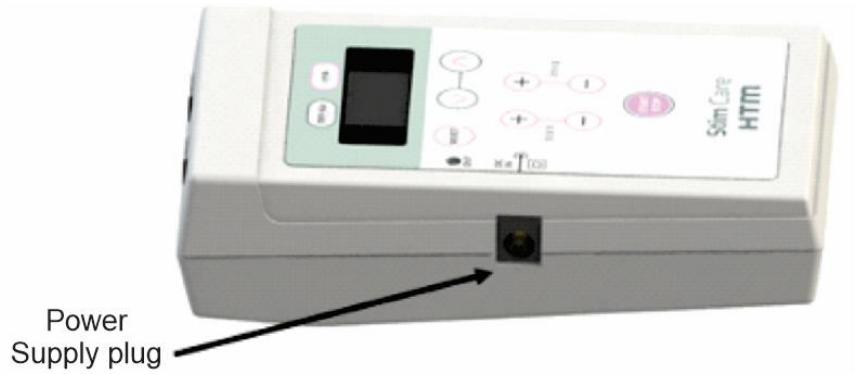
9.2.1 DESCRIPTION OF THE BACK OF THE Stim Care EQUIPMENT

Clip for Device Support
Clip to hold the device when using it on the move;

Note: Depending on the distance required for the movements, the equipment must be powered only with the battery.

Battery Compartment.
Battery placement compartment.

9.3 LEFT SIDE OF THE Stim Care EQUIPMENT



9.3.1 DESCRIPTION OF THE LEFT SIDE ENTRANCE OF THE Stim Care EQUIPMENT

1 - Input for Power Supply Connection (DC-IN)
External power supply plug input for mains power.

9.4 UPPER PART OF THE Stim Care EQUIPMENT

9.4.1 DESCRIPTION OF INPUTS AND OUTPUTS OF THE Stim Care EQUIPMENT

1 - Polarized Current Outputs
Output channels of polarized currents;

2 - Two-Phase Current Outputs
Two-phase current output channels.

10 Stim Care EQUIPMENT OPERATION

10.1 Stim Care EQUIPMENT OPERATION

After having installed the equipment according to the topics indicated in the Installation item and having read these instructions for use, you are ready to operate the equipment. Below is a step-by-step description of how the equipment can be operated.

1) Turning on the Equipment

Turn on the equipment using the On key, located on the equipment's panel. Immediately the Graphic Display will start displaying the splash screens. The first screen presented is the HTM Eletrônica logo.

Presentation screen, HTM Electronics logo

After a few moments, a screen containing the equipment name and software version are shown on the Display.

Splash screen, name Stim Care and software version (illustrative image)

2) Selecting the Operating Current

After displaying the presentation screens, the user can select and configure the desired operating current. By default, the first current displayed is TENS. To change the current options, just press the SELECT key until the corresponding field changes the display color, and then press the Up or Down keys to change the parameters.

Current selection screen

3) Selecting the Operation Mode

After selecting the current, the next step is to choose its operating mode, that is, which current stimulus mode will be. Select the NORMAL parameter by pressing the SELECT key until it changes the display color. With the parameter selected, press the Up or D own keys to determine the desired operating mode.

Operating mode selection screen

4) Selecting Duty Cycle or Pulse Width (Pulse Duration)

Duty Cycle (Cycle): This control determines the duty cycle of the clipping frequency. It varies between the following options:

- Russian 2500Hz: 2ms, 4ms, 10%, 33% or 50%;
- High Force 1000Hz: 2ms, 4ms, 10%, 33% or 50%.

Pulse Width or Pulse Duration (Width / Duration): This control determines the pulse width or duration for currents. It varies between the following options:

- TENS and FES: 50 to 600 μs;
- Lipolysis: 50 to 600 μs.

Select the CYCLE, WIDTH or DURATION parameter by pressing the SELECT key until its value changes the display color. With the parameter selected, press the Up or Down keys to change the parameters.

Pulse width selection screen

NOTE!
The WIDTH / DURATION or CYCLE parameters are changed according to the selected operating current automatically.

5) Selecting the Clipping Frequency

This control determines the repeat/trim frequency.
To optimize applications, the equipment automatically limits this variation, according to the selected operating mode. Select the FREQUENCY parameter by pressing the SELECT key until its value changes the display color. With the parameter selected, press the Up or Down keys to determine the desired clipping frequency.

Clipping frequency selection screen

6) Selecting the Application Time

This control determines the current application time.
After configuring the necessary parameters for the application, the user will be able to configure the desired treatment time. To do so, press the SELECT key until the TIME field changes its display color. With the parameter selected, press the Up or Down keys to increase or decrease the application time.

Application time selection screen

NOTE!
The programmed time regresses automatically and with automatic shutdown.

7) Selecting Rise, ON, Decay and OFF times

Rise ( ): Signal rise time - 0 to 10s;
ON ( ): Signal active time - 0 to 60s;
Decay ( ): Signal decay time - 0 to 10s;
OFF ( ): Signal idle time - 0 to 60s.

It varies between the following options:

- FES;
- High Force 1000Hz and Russian 2500Hz.

Select the Rise, ON, Decay or OFF parameter by pressing the SELECT key until the field changes display color. With the parameter selected, press the Up or Down keys to determine the signal times.

Rise time selection screen

ON time selection screen

Decay time selection screen

OFF time selection screen

NOTE!
For currents that do not have this option, the time settings fields will not be enabled.

8) Starting the Application

To start the treatment, press the START/STOP key. At this moment the OUT LED will light up, the time will start counting down and the “bargraph” will be displayed.

Application in progress screen

9) Channel Intensity (mA)

This control determines the current strength of each channel individually. It varies between the following options:

- TENS and FES: 1 to 100 mA;
- Russian 2500Hz and High Force 1000 Hz: 1 to 50 mA;
- Lipolysis (Transcutaneous): 1 to 100 mA;
- Lipolysis (Percutaneous): 1 to 30 mA;

- Microgalvanic: 50 to 999 μA;
- Galvanic: 100 μA at 3 mA;
- MENS: 50 to 999 μA.

Up and Down keys of the desired channel. The intensity values will be displayed on the equipment Display.

Current intensity screen

10) Finishing the Application

After counting the application time, the equipment resets the output doses and displays the message END OF APPLICATION on the Display, indicating that the application is zeroed. To exit this screen, press any key.

Application closing screen

NOTE!

☑ During the application of currents, at no time should the patient be exposed to uncomfortable intensities;

☑ During current applications, a perfect coupling must be ensured between the electrode and the treatment region. This coupling must be done using a coupling medium, such as a gel.

11) Saving New Protocols

The **Stim** Care equipment allows the recording of new custom protocols. To save new protocols, after configuring all the variables, press the SELECT key until the

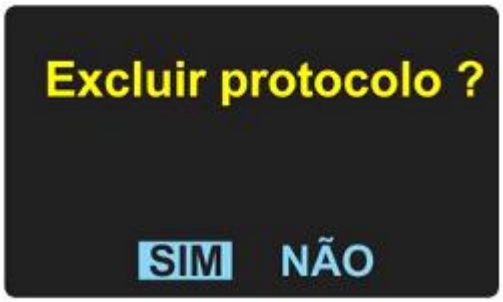
SAVE field changes its display color, press the Up or Down keys to proceed in the storage fields, select the desired field and press SELECT.

To delete saved protocols, just press SELECT key until DELETE field changes its display color, press Up or Down keys to proceed with protocol deletion. Using the SELECT key, choose between YES or NO and confirm with the Up or Down keys.

Protocol save screen

Storage screen

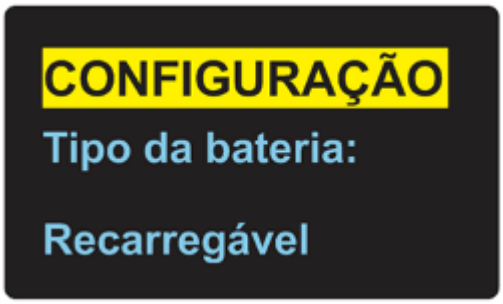
Delete protocol screen



Delete screen

12) Battery type configuration

Press the Up key until you reach the battery setting screen.



Press SELECT key to enable battery type field.

Press the Up key to select the “Rechargeable” type or the Down key to select the “Non-Rechargeable” type, depending on the chosen battery type.

To exit the drum setup screen, press the SELECT key again, then the Down key.

Incorrect battery type setting can create a risk of battery leakage or explosion. Only rechargeable batteries can be recharged.

The battery type chosen is saved in the device's memory. If you want to use another battery model, you must perform the battery configuration procedures described above again.

13) Battery Charge Level Indications

These indications assist in monitoring battery charge levels. When the message CONNECT SOURCE appears on the display, it means that the battery is low.

The equipment also makes it possible to recharge the battery using its own dual voltage power supply. To do this, simply connect the power supply plug to the equipment's power input and to the electrical outlet. Before carrying out the battery recharging process, verify that the battery being used is really a 9Vdc NiMH rechargeable battery.

Indication screen to recharge the battery

Indication screen loading

Battery charged display screen

NOTE!
Do not stop charging the battery until the display indicates that it has been fully charged, this increases battery life and speeds up the charging process. If battery charging is interrupted, the charging process starts again from the beginning.

Only 9Vdc NiMH rechargeable batteries can be recharged. Check the battery type before starting the charging process.

Never attempt to recharge 9Vdc alkaline batteries.

Whenever you are using the equipment with the bivolt power supply plugged into the electrical outlet, make sure that the equipment does not have a 9Vdc alkaline battery connected.

14) Language selection

Through the main menu it is possible to access the language selection option, for this, use the parameter selection Up key to advance to the last configuration. Press the SELECT key to advance and using the Up and Down keys choose the desired language.

Selected Portuguese language at display screen

Selected English language at display screen

Selected Spanish language at display screen

11 EQUIPMENT MAINTENANCE

WARNING

It is noteworthy that the use and/or destination of the equipment for the purpose of leasing, loaning or sharing between professionals or clinics, and/or similar conditions, demands greater care on the part of users, as in these situations the device is subjected to frequent transport. , movements, vibrations, mechanical shocks; greater number of usual cycles of engagement and disengagement of connectors, plugs and cables; longer usage time; minor care for cleaning and/or periodic maintenance of the equipment. In any of these situations, the warranty conditions will be maintained, provided that the periodic calibration is carried out in accordance with the equipment instructions for use and the technical assistance does not verify that the defect arises from natural wear and tear of its own use and/or misuse caused by lack of skill and/or care, which is common in these cases.

11.1 CORRECTIVE MAINTENANCE

Below are listed some problems that may eventually happen with the equipment and their possible solutions. If your device has any of the following issues, follow the instructions to try to resolve it. If the problem is not resolved, contact an HTM Eletrônica Technical Assistance.

1st) PROBLEM: The equipment does not turn on.

Reason 1: The installed 9Vdc battery is empty.

Solution 1: Make sure the battery is inserted, is alkaline or 9Vdc NiMH rechargeable, and is charged.

Reason 2: The mains socket where the equipment is connected has no power.

Solution 2: Make sure the product is plugged into an electrical outlet. For example, plug other equipment into the outlet to see if it works.

Reason 3: The voltage of the outlet where the equipment is connected is not within the range of 100 to 240V~, specified for the equipment's external power supply.

Solution 3: Make sure the outlet voltage is within the working voltage range of the power supply.

2nd) PROBLEM: The equipment is stimulating too little (“weak”).

Reason 1: The voltage of the outlet where the equipment is connected is not within the range of 100 to 240V~, specified for the equipment's power supply.

Solution 1: Make sure the outlet voltage is within the source working voltage range.

Reason 2: The inserted battery has been used for a long time and is discharged.

Solution 2: Replace the battery with a new one or a charged one.

Reason 3: The electrodes are not well fixed.

Solution 3: Check that the amount of gel placed on the electrode is sufficient to attach them and fix them on the patient using an adhesive tape.

3rd) PROBLEM: One of the channels is not stimulating.

Reason 1: The application cable has a problem.

Solution 1: Check if it really is the application cable that has the problem, for example, placing another cable of the same type of current in the channel that is not working.

11.2 PREVENTIVE MAINTENANCE

11.2.1 CAUTION WITH ELECTRODES

It is normal, after some time of use, for silicone electrodes to wear out, losing their electrical conductivity characteristics. With this, stimulation is compromised and the feeling that the device is weak is common.

In some cases, it is also possible to form points (protrusions) where the current density can be high, causing discomfort to the patient.

It is recommended to replace the silicone electrodes, at most, every 6 months, even if they are not used and in cases of intense use, the recommendation is to change them monthly.

Silicone electrodes can also show cracks, in which case the replacement must be immediate.

11.2.2 CONNECTION AND POWER CABLES

The user should inspect the electrode connection cable and the power supply cable daily for possible damage (eg, cuts, dryness). In case of any kind of problem, contact HTM ELETRÔNICA to arrange the replacement of parts and calibration of the equipment.

11.2.3 CLEANING THE CABINET

When necessary, clean the cabinet of your equipment with a soft cleaning cloth. Do not use alcohol, thinner, benzine or other strong solvents, as they may damage the finish of the equipment.

11.2.4 CLEANING THE ELECTRODES

☑ After using the silicone electrodes and the tips and pen electrodes, wash them with running water and neutral soap;

☑ After using the electrodes with a vegetable sponge, wash them with running water.

Do not use the accessories without proper hygiene!

11.2.5 CALIBRATION

The **Stim** Care equipment must be calibrated at least every 12 months.

11.3 SENDING EQUIPMENT TO TECHNICAL ASSISTANCE

If your equipment is not working according to the characteristics of this instructions for use and after following the instructions in the CORRECTIVE MAINTENANCE item without success, contact HTM Eletrônica, which will inform the nearest Authorized Assistance Center.

Along with the equipment, a letter must be sent reporting the problems presented by the equipment, contact details and address for sending the equipment.

NOTE!
When contacting HTM Eletrônica, it is important to inform the following data:

- ☑ Equipment model;
- ☑ Equipment serial number;
- ☑ Description of the problem that the equipment is presenting.

ATTENTION!

Do not want to repair the equipment or send it to a technician not accredited by HTM Eletrônica, as removing the seal will void the warranty, in addition to posing a risk of electric shock. If you want to send the equipment to a technician you trust, HTM Eletrônica can supply the parts for maintenance, but will no longer be responsible for the equipment and the effects caused by it.

11.4 ENVIRONMENT

When the device and its accessories have reached the end of their useful life, dispose of them in a way that does not harm the environment. Contact companies that work with selective collection to perform a recycling procedure.

It should not be released directly into the environment, as some of the materials used contain chemical substances that can be harmful to the environment.

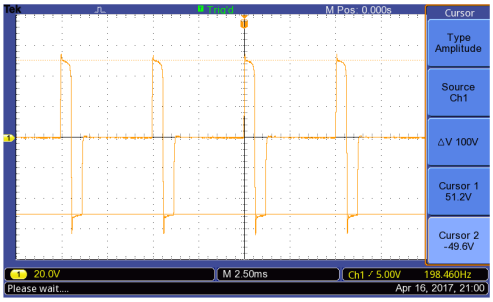
12 EQUIPMENT TECHNICAL SPECIFICATIONS

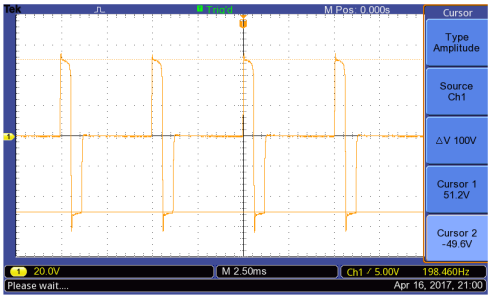
12.1 POWER SUPPLY TECHNICAL CHARACTERISTICS

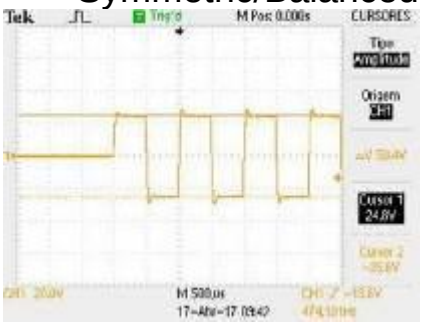
AC Power Voltage:	100-240 V~ ± 10%
Power Voltage Frequency:	50/60 Hz ± 10%
Input Power:	20 VA ± 10%
DC Output Voltage:	9 Vdc ± 20%
Weight:	0,265 kg
Dimensions (W x H x D)	45 x 65 x 60 mm

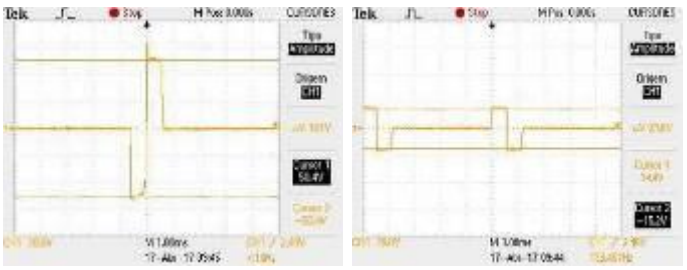
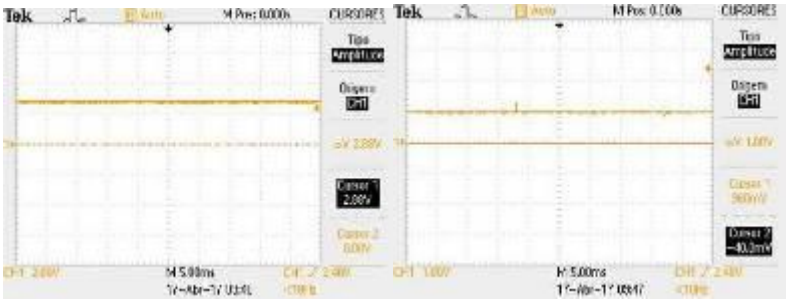
12.2 TECHNICAL CHARACTERISTICS OF THE Stim Care EQUIPMENT

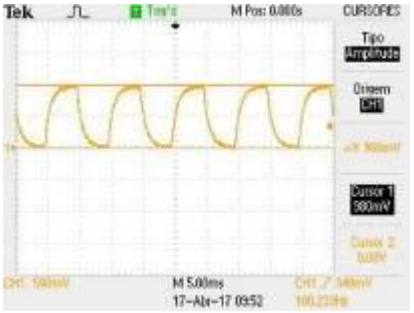
Equipment:	Stim Care
Origin:	HTM Indústria de Equipamentos Eletro-Eletrônicos LTDA
Technical name and function:	Neuromuscular Stimulator
Food:	Alkaline Battery 9 Vdc / rechargeable Ni-MH 9 Vdc
Maximum DC Power Consumed:	20 VA
TIMER:	1 min to 60 min ±10%

TENS Mode	**Normal, VIF, VF, Acupuncture, Conventional, Short-Intensive, and BURST**
Current Type:	Symmetric/Balanced 
Number of Output Channels:	2 (independent amplitudes)
Maximum Intensity:	100 mA ± 20%
Load Impedance: *The increase in impedance implies a decrease in current.	1000 Ohms 10%*
Pulse Repetition Frequency:	Normal: 1 Hz to 200 Hz ± 10% VIF: 1 Hz to 200 Hz ±10% AUT VF: 1 Hz to 200 Hz ±10% AUT Acupuncture: 1 Hz to 10 Hz ± 10% Conventional: 40 Hz to 150 Hz ± 10% Brief-Intense: 100 Hz to 150 Hz ± 10% BURST: 50 Hz to 150 Hz ± 10%
Pulse Width / Pulse Duration:	Normal: 50 μs to 600 μs ± 10% VIF: 50 μs to 600 μs ± 10% AUT FV: 50 μs to 600 μs ± 10% Acupuncture: 180 μs to 250 μs ± 10% Conventional: 50 μs to 80 μs ± 10% Brief-Intense: 150 μs to 250 μs ± 10% BURST: 100 μs to 200 μs ± 10%
BURST:	8 Hz ± 10%
FES Mode	**Synchronized, Reciprocal, Synchronized VIF and VF and Reciprocal VIF and VF**

Current Type:	Symmetric/Balanced 
Number of Output Channels:	2 (independent amplitudes)
Maximum Intensity:	100 mA ± 20%
Load Impedance: *The increase in impedance implies a decrease in current.	1000 Ohms 10%*
Pulse Repetition Frequency:	1 Hz to 200 Hz ± 10%
Pulse Width:	50 μs a 600 μs ±10%
RISE time:	1 s 10 s ± 10%
ON time:	1 s 60 s ± 10%
DECAY time:	0 s to 10 s ± 10%
OFF time:	1 s 60 s ± 10%
Modes: RUSSIAN and HIGH	**Continuous, Synchronized and Reciprocal**

Current Type:	Symmetric/Balanced 
Number of Output Channels:	2 (independent amplitudes)
Maximum Intensity:	HIGH: 50 mA ± 20% RUSSIAN: 50 mA ± 20%
Load Impedance: *The increase in impedance implies a decrease in current.	1000 Ohms 10%*
Carrier Frequency:	HIGH: 1.000 Hz ± 10% RUSSIAN: 2.500 Hz ± 10%
Clipping Frequency:	HIGH: 1 Hz to 120 Hz ± 10% RUSSIAN: 1 Hz to 200 Hz ± 10%
Duty Cycle:	HIGH: 10%, 33%, 50%, 2ms and 4ms ± 10% RUSSA: 10%, 33%, 50%, 2ms and 4ms ± 10%
RISE time:	1 s 10 s ± 10%
ON time:	1 s 60 s ± 10%
DECAY time:	0 s to 10 s ± 10%
OFF time:	1 s at 60 s ± 10%
LIPOLYSIS Mode	**Transcutaneous and Percutaneous**

Current Type:	Symmetric/Balanced 
Number of Output Channels:	2 channels (independent ranges)
Maximum Intensity:	100 mA ± 20% (Transcutaneous) 30 mA ± 20% (Percutaneous)
Load Impedance: *The increase in impedance implies a decrease in current.	1000 Ohms 10%*
Pulse Repetition Frequency:	1 Hz to 200 Hz ± 10%
Pulse Width:	50 μs a 600 μs ± 10%
GALVANIC / MICROGALVANIC Mode	**Normal and Inverted**
Current Type: Polarized* *DC component: see output parameters 	
Number of Output Channels:	2 channels (independent range)
Maximum Intensity:	Galvanic: 3 mA ± 20% Microgalvanic: 1000 µA ± 20%
Load Impedance: *The increase in impedance implies a decrease in current.	1000 Ohms 10%*

Carrier Frequency:	Pure
MENS Mode	**Normal, Inverted and Automatic**
Current Type: Polarized* *DC component: see output parameters	
Number of Output Channels:	2 channels (independent ranges)
Maximum Intensity:	1000 µA ± 20%
Load Impedance: *The increase in impedance implies a decrease in current.	1000 Ohms 10%*
Pulse Repetition Frequency:	0,1 Hz to 1000 Hz ± 10%
Polarity Inversion:	Every 2,5 seconds
Equipment Weight without Accessories	0,200 kg
Dimensions (W x H x D):	70 x 30 x 130 mm
Operating Temperature:	10°C to 30°C
Atmospheric operating pressure:	70 kPa to 106 kPa
Storage and transport temperature:	-20ºC to 60ºC

Atmospheric pressure of storage and transport:	50 kPa to 106 kPa
Recommended relative humidity range for storage, transport and operation:	10 to 60%
Shipping Packing:	Use the Original

12.3 ELECTROMAGNETIC EMISSIONS

Manufacturer's Guide and Declaration - Electromagnetic Emissions		
The **Stim** Care equipment is intended for use in the electromagnetic environment specified below. It is recommended that the customer or user ensure that it is used in such an environment.		
RF emission ABNT NBR IEC CISPR 11	Group 1	The **Stim** Care equipment uses RF energy only for its internal function. However, its RF emissions are very low and it is not likely to cause any interference to nearby electronic equipment.
RF emission ABNT NBR IEC CISPR 11	Class A	The **Stim** Care equipment is suitable for use in all establishments other than residential and those directly connected to the public low-voltage electricity distribution network that supplies buildings for domestic use.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	According	

12.4 ELECTROMAGNETIC IMMUNITY

Manufacturer's Guide and Declaration - Electromagnetic Immunity			
The **Stim** Care equipment is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.			
Immunity Assay	ABNT NBR IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidelines.
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV per contact ±8kV by air	±6kV per contact ±8kV by air	Flooring should be wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast Electrical Transients / Pulse Train (" Burst ") IEC 61000-4-4	±2kV on power lines ±1kV on input/output lines	±2kV on power lines	It is recommended that the quality of the power supply be that of a typical hospital or commercial environment. It has no output lines.
outbreaks IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV line(s) to line(s)	It is recommended that the quality of the power supply be that of a typical hospital or commercial environment.
Voltage dips, interruptions, shorts and voltage variations on input power lines IEC 61000-4-11	< 5% UT (> 95% voltage drop across UT) for 0.5 cycle. 40% UT (60% voltage drop in UT) for 5 cycles. 70% UT (30% voltage drop in UT) for 25 cycles. < 5% UT (> 95% voltage drop in UT) for 5 seconds.	< 5% UT (> 95% voltage drop across UT) for 0.5 cycle. 40% UT (60% voltage drop in UT) for 5 cycles. 70% UT (30% voltage drop in UT) for 25 cycles. < 5% UT (> 95% voltage drop in UT) for 5 seconds.	It is recommended that the quality of the power supply be that of a typical hospital or commercial environment. If the user requires continued operation during a power outage, it is recommended that the **Stim** Care equipment be powered by an uninterruptible power supply.
Magnetic field at power frequency (50/60Hz) IEC 61000-4-8	3A/m	3A/m	Magnetic fields at the power frequency should be at levels characteristic of a typical location in a typical location in a typical hospital or commercial environment.

Manufacturer's Guide and Declaration - Electromagnetic Immunity			
The **Stim** Care equipment is intended for use in the electromagnetic environment specified below. It is recommended that the customer or user ensure that it is used in such an environment.			
Immunity Assay	ABNT NBR IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidelines.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz up to 80MHz 3 V/m 80MHz up to 2.5GHz	3 Vrms 3 V/m	It is recommended that portable or mobile RF communications equipment not be used near any part of the portable electrostimulator family equipment, including cables, with a separation distance less than the recommended one, calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1,2\sqrt{P}$ $d=1,2\sqrt{P}$ 80MHz up to 800MHz $d=2,3\sqrt{P}$ 800MHz up to 2,5GHz where P is the rated maximum output power of the transmitter in Watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). It is recommended that the field strength established by the RF transmitter, as determined through an electromagnetic on-site inspection, be less than the compliance level in each frequency range. Interference may occur around equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800MHz 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.			
The. Field strengths established by fixed transmitters such as base stations, telephone (cellular/cordless) land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it is recommended to consider an electromagnetic site survey. If the field strength measurement at the location where the portable electrostimulator family equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional procedures may be necessary, such as reorientation or relocation. B. Over the frequency range 150kHz to 80MHz, the field strength should be less than 3V/m.			

12.5 RECOMMENDED SEPARATION DISTANCES BETWEEN RF, PORTABLE AND MOBILE COMMUNICATION EQUIPMENT AND THE Stim Care EQUIPMENT

Recommended separation distances between portable and mobile RF communications equipment and the Stim Care equipment

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

Rated maximum output power of the transmitter (W)	Separation distance according to transmitter frequency (m)		
	150kHz up to 80MHz $d=1,2\sqrt{P}$	80MHz up to 800MHz $d=1,2\sqrt{P}$	800MHz up to 2,5GHz $d=2,3\sqrt{P}$
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 with a maximum rated output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the transmitter frequency, where P is the maximum rated output power of the transformer in watts (W), according to the transmitter manufacturer.

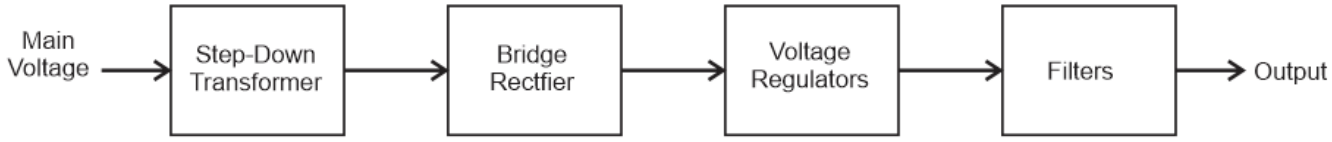
NOTE1: At 80MHz and 800MHz, separation distance for the higher frequency range applies.

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

12.6 Stim Care EQUIPMENT OPERATION

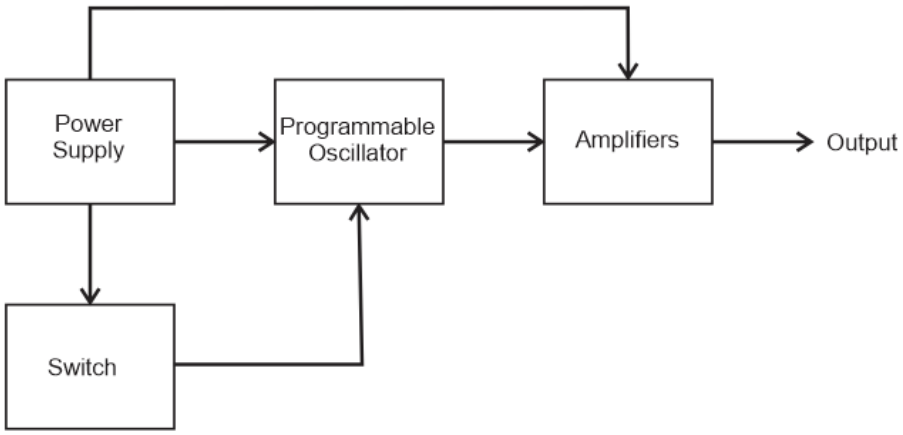
The operation of the Stim Care equipment can be understood from the following block diagram.

Equipment Power Supply Block Diagram



Stim Care Block Diagram

Block diagram of the equipment **Stim** Care



Stim Care Block Diagram

12.7 Stim Care CLASSIFICATION EQUIPMENT AS NBR IEC 60601-1 and NBR IEC 60601-2-10

1) According to the type of protection against electric shock:
Class II equipment and internally energized;

2) According to the degree of protection against electric shock:
Applied part type BF;

3) According to the degree of protection against harmful penetration of water:
IP20 common equipment - (closed equipment without protection against water penetration);

4) According to the degree of safety in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide:
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide;

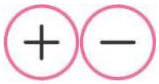
5) According to the operating mode:
Equipment for continuous operation.

12.8 DESCRIPTION OF SYMBOLOGIES USED IN THE SOURCE OF THE EQUIPMENT

Symbol	Description
	Alternating Current
	Power Plug
	CLASS II EQUIPMENT
	Not to be disposed of in commercial or household waste

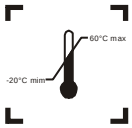
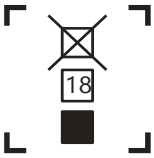
12.9 DESCRIPTION OF SYMBOLOGIES USED IN THE EQUIPMENT

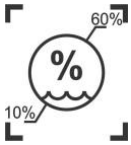
Symbol	Description
	General warning symbol
	APPLIED PART TYPE BF
	CLASS II EQUIPMENT
	9Vdc Source Input DC IN Connector
	Direct current

	Consult Accompanying Documents
	Manufacturing date
	Signal rise time
	Signal active time
	Signal drop-off time
	Signal idle time
	Selection key
	Key to increment parameters and display navigation
	Key for decrementing parameters and display navigation
	Key to start/stop the application
	Keys for increasing and decreasing channel intensity
	Key to turn on the device
	Key to turn off the device
	Low battery charge
	Bateria com carga baixa

	Charged battery

12.10 DESCRIPTION OF SYMBOLOGIES USED IN PACKAGING

Symbol	Description
	This side up
	Fragile
	Temperature limit
	Protect against rain
	Maximum equipment box stacking: 18 boxes
	Maximum stacking of the equipment box together with the accessories box: 6 boxes
	Keep away from sunlight
	Do not dispose of in household waste

	Recyclable packaging
	Batch code
	Humidity limit

12.11 CIRCUITS DRAWINGS, PARTS LIST, COMPONENTS AND CALIBRATION INSTRUCTIONS

HTM Ind. de Equip. Eletro-Eletrônicos Ltda. makes available, upon agreement with the user, circuit diagrams, parts list, components and calibration instructions and other information necessary to the user's qualified technical personnel to repair parts of the Equipment that are designated by HTM as repairable.

12.12 BIOCOMPATIBILITY DECLARATION

We declare under our sole responsibility that all materials used in APPLIED PARTS (as defined in the NBR IEC 60601-1 standard) in the equipment of the portable electrostimulator family have been widely used in the medical field over time, thus ensuring their biocompatibility.

13 WARRANTY CERTIFICATE

13.1 SERIAL NUMBER / WARRANTY START DATE

Your HTM Eletrônica equipment is covered against manufacturing defects, respecting the considerations established in this instructions for use, for a period of 18 consecutive months, these months being divided into:

First 3 months: legal guarantee.
15 months remaining: additional warranty granted by HTM Eletrônica.

The warranty will start from the date the equipment is released by the HTM Eletrônica shipping department.

All equipment warranty services must be provided by HTM Eletrônica or by a Technical Assistance authorized by it at no cost to the customer.

The guarantee ceases to be valid if:

☑ The equipment is used outside the technical specifications mentioned in this instructions for use;

☑ The equipment serial number is removed or changed;

☑ The equipment is dropped, wet, scratched, or otherwise mistreated;

☑ The equipment seal is broken or if HTM Eletrônica Technical Assistance finds that the equipment has been altered or repaired by technicians not accredited by HTM Eletrônica.

Transporting the equipment during the legal warranty period:

☑ If the equipment, in the evaluation of HTM Technical Assistance, does not present manufacturing defects, maintenance expenses will be charged.

The legal guarantee (3 months) covers:

☑ Manufacturing defects in the device and accompanying accessories.

The additional warranty (15 months) covers:

☑ Device manufacturing defects.

The additional warranty does not cover:

☑ All terms not covered by the legal guarantee;

Some examples of damage that the warranty does not cover:

☑ Equipment damage due to transport and handling accidents. These damages include: scratches, dents, broken printed circuit board, cracked cabinet, etc.;

☑ Damage caused by natural disasters (e.g., lightning);

☑ Displacement of a technician from HTM Eletrônica to other municipalities with the intention of performing maintenance on the equipment;

☑ Electrodes, application cables or any other accessory subject to natural wear during use or handling.

NOTE!

☑ HTM Eletrônica does not authorize any person or entity to assume any other responsibility related to its products than those specified in this term;

☑ For your peace of mind, keep this Warranty Certificate and Instructions for use;

☑ HTM Eletrônica reserves the right to change the characteristics of its instructions for uses and products without prior notice.