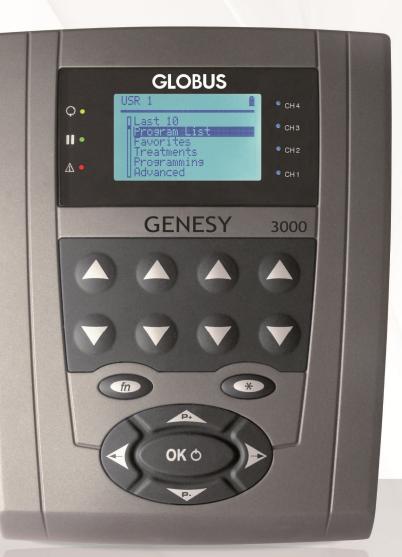


# ELETTROSTIMOLATORI

🚺 Manuale di utilizzo

# GENESY 3000



(F

0476

# **DEAR CUSTOMER**

# THANK YOU FOR CHOOSING A GLOBUS PRODUCT. WE REMAIN AT YOUR DISPOSAL FOR ANY ASSISTANCE OR ADVICE YOU MAY NEED

DOMINO s.r.l. Via Vittorio Veneto 52 31013 - Codognè - TV - Italy Tel. (+39) 0438.7933 Fax. (+39) 0438.793363 e-mail: info@globuscorporation.com www.globuscorporation.com

## Table of contents

TECHNICAL FEATURES	6
Device	6
Disposal of the device	8
Declaration of conformity	8
INTENDED USE	8
The risk class of the device is IIb	8
EQUIPMENT	9
LABELLING AND SYMBOLS	11
Panel and keyboard	15
Display and interface	16
PREPARATION TO THE USE OF THE DEVICE	16
Warnings before the use	17
How to connect the cables	18
Connection of the electrodes	18
Battery	19
Safety precautions	19
Contraindications	20
Side effects	21
USER GUIDE OF THE DEVICE	22
For a correct use of the device, proceed as follows:	22
Program List menu	22
"Last 10" Menu	24
"Treatments" Menu	25
"Programming" Menu	26
Advanced Menu	27

PROGRAM LIST	32
GENERAL NOTES ON ELECTRODE POSITIONING	39
ACTION PRINCIPLES	48
Muscular electrostimulation	48
Stimulation intensity	49
MAINTENANCE AND CLEANING	54
Device	54
Battery	54
Accessories	54
WARRANTY	56

# **TECHNICAL FEATURES**

#### Device

Size: Weight: Case: Protection level:

Use Conditions

Temperature: Max. relative humidity: Atmospheric pressure: 220x170x60 mm 790 g. ABS IP 20

> From 0°C to 35°C from 15% to 93% from 700 hPa to 1060 hPa

#### Storage and transport conditions

Temperature:	From -10°C to 45°C
Max. relative humidity:	30% - 75%

The values represent the limits allowed if the product or the accessories are not in their original package.

#### Technical features of EMS and TENS currents:

Channels available:	Channels 1-2-3-4	
Constant current: Yes		
Intensity:	0-120 mA with 1000 Ohms load	
Waveform: rectangular, biphasic, symmetrical, compensated		
Work frequency:	0.3-150 Hz	
Recovery frequency:	0.3-150 Hz	
Pulse amplitude:	50-450 µs	
Working time: from 1 to 30 seconds		
Working time: from 0 to 1 minute		
Frequency modulation range:	Cont. variation from 1 to 150 Hz	
Minimum modulation time:	3 seconds	
Period modulation range:	Continuous variation from 50 to 450 µs	
Microcurrents		
Channels available:	Channels 1-3	
Constant current:	Yes	
Minimum frequency:	5 Hz	
Maximum frequency:	200 Hz	
Min. intensity:	0 µA/1000 Ohm Step 10 µA	
Max. Intensity:	800 µA/1000 Ohm	
Period value: included between 1 and 250	µ seconds	

REV. 3 del 04.11.2020

#### Interferentials:

Channels available: Max. Intensity: Carrier frequency:

Frequency modulation: Type of oscillation:

#### Russ:

Channels available: Max. Intensity: Carrier frequency: Mod. wave:

#### **Denervated muscles:**

Channels available: Max. Intensity: Pulses:

#### lonophoresis:

Available outputs: Constant current: Min. intensity: Max. Intensity:

Min. time: Max. time:

Power supply unit: Brand: model: PRI: SEC: Polarity: **D-C-O** 

#### Battery

Battery pack:

Channels 1-3 - 60 mA 2500 Hz 4000 Hz 10000 Hz 0 - 200 Hz Variable in duration and period

Channels 13 60 mA 1250 - 2500 Hz 6, -12, -25, -100 Hz

Channels 1-3 60 mA Triangular 1000 ms, Rectangular/trapezoidal 500 ms

Channel 1 Yes 0 mA/1000 Ohm 10 mA/1000 Ohm step 0.1 mA/1000 Ohm 1 minute 99 minutes

GlobTek GTM4160-2512 100-240V 50-60Hz 0.6A max 12V ---- 2.08A

Ni-MH 7.2V 1 Ah

### Disposal of the device

Do not throw the device or parts of it into the fire; dispose of the product in the specialized centers and respecting the regulations in force in your Country. When the product has to be disposed of, the user can give it back to the retailer when purchasing a new device.

A correct separate waste collection or the compliance with the above-mentioned prescriptions contribute to avoiding possible negative effects on the environment and the health and promote the reuse and/or recycle of the materials of which the device is composed. The illegal disposal of the product entails the application of administrative fines according to applicable regulations.

### Declaration of conformity

The device has been manufactured in compliance with applicable technical standards and has been certified, in compliance with Directive 93/42/EEC as amended by directive 2007/47 on medical devices, by the Notified Body Kiwa Cermet Italia, Via Cadriano 23, 40057 Granarolo Dell'Emilia (BO) Italy (n. 0476), in order to ensure product safety.

# **INTENDED USE**

The estimated usable life of the product is 5 years. It is advisable to return the device to the producer and/or authorized center to perform security and maintenance checks every 2 years. The number of treatments depends on the battery charge.

# The risk class of the device is IIb.

The device is intended for:

- Antalgic electrotherapy through peripheral nervous system stimulation;

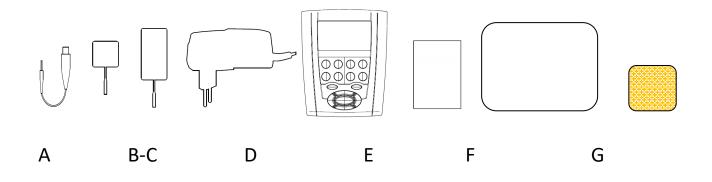
- Muscular electrostimulation in order to reduce atrophy, spasticity and to increase the muscular power.

E3K (Genesy 3000) devices are not intended for domestic purposes and are designed to be used in the following operating environments:

- clinics;

- physiotherapy centers;
- rehabilitation in general;
- general pain treatments (medical treatments);

The use of the device is permitted to doctors and physiotherapists.



The electrostimulation device is supplied with all the necessary cables and electrodes; therefore, when you open the package, check that the basic equipment is complete. If some elements are missing, contact your authorized retailer immediately.

A. 4 coloured cables for electrode connection(per for EMS,TENS,DENERVATED, INTERFERENTIALS, RUSSIAN) and 2 gray cables for electrode connection (for MICROCURRENTS and IONOPHORESIS treatments)

- B. 4 self-adhesive, re-usable electrodes (50 x 50 mm)
- C. self-adhesive, re-usable electrodes (50 x 90 mm)
- D. Battery charger (see technical features)
- E. Unity
- F. User Manual
- G. Carrying case
- H. Ionophoresis kit

#### **Equipment description**

REF G0464 - Electrodes Myotrode Plus (50x50 mm). Package with 4 adhesive electrodes. Electrodes can be used multiple times on the same patient. We recommend the use of these electrodes for small surfaces such as upper limbs, calves, cervical area...

REF G0464 - Electrodes Myotrode Plus (50x50 mm). Package with 4 adhesive electrodes. Electrodes can be used multiple times on the same patient. We recommend the use of these electrodes for large surfaces such as thighs, abdomen, gluteus...

### Accessories that are not included in the equipment (to be purchased separately)

The device can be combined with optionals some accessories(see the technical features on our websitewww.globuscorporation.com <u>www.globuscorporation.com</u>). To purchase these accessories, please contact your dealer.

REF	Name	Description	
G1188	VAGINAL PROBE	Probe for the treatment of incontinence and for the reinforcement of the pelvic floor.	
G0757	Anal probe	Probe for the treatment of incontinence and for the reinforcement/relaxation of the pelvic floor.	
G1156	Motor point pen	It helps finding the best positioning of the electrodes	
G1309	G-trode Handpiece	Bipolar G-PULSE head	
G0479	Kit conductive elastic bands for thighs	Kit conductive elastic bands for thighs Bands can be used instead of electrodes, and are recommended for aesthetic and beauty treatments.	
G0480	Kit conductive elastic bands for thighs and arms Fitness Top	Kit conductive elastic bands for thighs and arms Bands can be used instead of electrodes, and are recommended for aesthetic and beauty treatments.	
G0487	Fast Band	Abdominal band for treatment on abdomen, gluteus and back - 98 cm	
G0489	Fast Pad	Special reusable electrodes, specifically suitable for aesthetic treatments on thighs and gluteus.	
G0890	Medium ionophoresis electrode	Carbon electrode + pouch 50x50 mm	
G0885	Big ionophoresis electrode	Carbon electrode + pouch 60x85 mm	
G0488	Fast body kit	fast band + fast pad	
G0439	Kit 2 splitting cables	This accessory is used to split the cables in order to use more electrodes at the same time.	

# LABELLING AND SYMBOLS

	It refers to the manufacturer
	Warning The device emits current values over 10 mA or10V
Ť	Keep the device dry
<b>CE</b> 0476	This symbol indicates that the device complies with the directives on medical devices (93/42/EEC 47/2007/EEC). The number of the notified body is 0476.
	It indicates that this is a class II device.
*	It indicates that this device has BF-type applied parts.
	WEEE symbol (Waste of Electrical and Electronic Equipment). Recycling symbol. The WEEE symbol used for this product indicates that it cannot be treated as a household waste. The proper disposal of the product will contribute to protecting the environment. For further information on the recycling of this product, please contact the concerned office of your local body, the household waste management company or the store where the product was purchased.
ROHS	It indicates that the product has been designed in compliance with the directive $2011/65/EEC$
<b>E</b>	It informs the operator that s/he must read the manual before using the device.
0	It informs the client of the compulsory conduct
	It indicates the ideal temperature for the storage and transportation of the product.
IP20	It indicates water protection

Model	Indicates the battery charger model	
PRI	Input electric features of the battery charger	
SEC	Output electric features of the power supply	
Nerve and Muscle stimulator	It indicates the device type	
Input power	Input electric features of the device for battery charging	
Input battery	Features of the electric power supply from internal battery	
Output	Output, indicates the maximum value of current emitted by the device	
SN	It indicates the serial number of the device.	
Internal battery	Indicates the features of the battery pack inside the device	
	It refers to the expiry date of the product	
LOT	It refers to the production lot	
$\sim$	It refers to the manufacturing date.	
	It indicates the pressure of the environment in which the device and the accessories are transported and stored.	
<u>%</u>	It indicates the humidity of the environment where the device and its accessories are used and stored	
RH	It indicates the percentage of storage humidity	
PE	Symbol for polythene	

#### Device

REV. 3 de



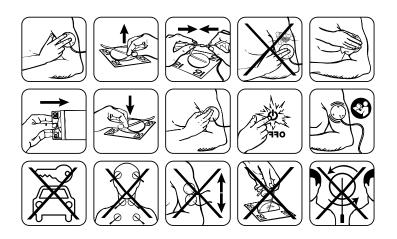


12



#### Accessories Electrodes

	It indicates the dimensions of the electrode
	It indicates the number of electrodes contained in the package
REF	It indicates the product code
CE	It refers to product certification and indicates that it complies with directive 2001/95/EC updated as 2014/357/EU
80.6°F 41.0°F + 5°C	It indicates the storage temperature of the electrodes



Clean and degrease the skin. Do not apply the electrode on wounds or injured skin. Connect the cable connector to the electrode connector. Remove the electrode. Apply on the skin.

Start the program.

At the end, turn off and put the electrode back in the package.

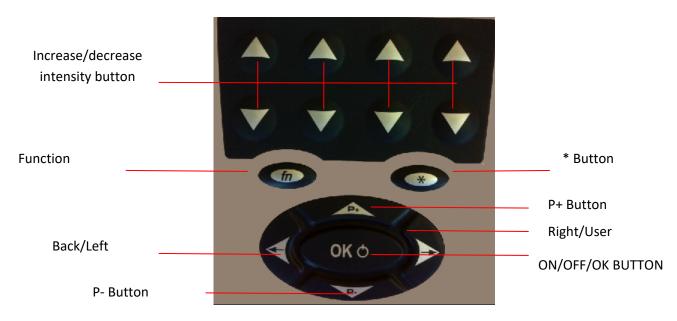
Electrodes are for personal use.

Do not remove the electrode by grabbing the connector.

Electrodes should not touch each other.

Do not apply the electrodes on the temples, the neck and in a transthoracic way. Do not leave the electrodes in the car.

#### Panel and keyboard



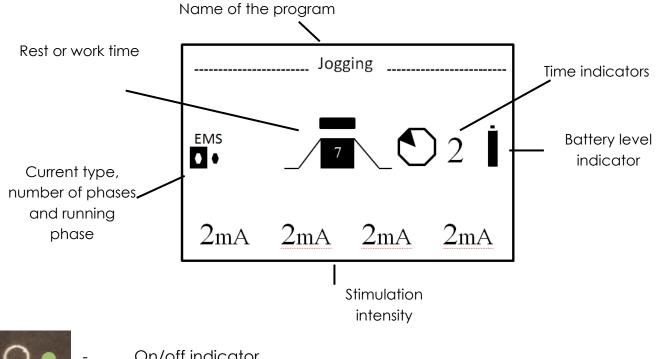
NOTE: when the 3" message appears, it means that by holding the button down for 3 seconds the function is activated.

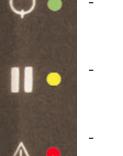
ON/OFF/OK BUTTON	It confirms the selection. It pauses the running program. 3" = Turn On/Off
LEFT/BACK Button	To scroll the selection left. To go back to the previous selection. 3" = It returns to the previous phase while the program is running.
P+ Button	It moves the selection upwards. It increases the intensity of the 4 channels simultaneously, while a program is running
P- Button	It moves the selection downwards. It increases the intensity of the 4 channels simultaneously, while a program is running
RIGHT/USER button:	It moves the selection to the right. 3" = It moves to the next phase, while a program is running
* Button	It starts and stops the contraction while "Action Now" programs are running (where "Action Now" programs are included).

**Fn (Runtime) button** If pressed together with other buttons, it permits the user to modify their function. Moreover, it selects Runtime mode (editing time, frequency and amplitude)

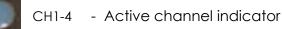
It increases/decreases the stimulation intensity of the Intensity button corresponding channel.

#### **Display and interface**





- On/off indicator
- PAUSE indicator (during the treatment)
  - General error indicator. If the led turns on, check the connections between the cables and the electrodes. If the light is still on, contact the customer care.



# PREPARATION TO THE USE OF THE DEVICE

For maximum safety, the device must be used following the rules and the limitations of the user manual.

The manufacturer declines all responsibility with reference to a different use from what is indicated in this manual.

The full or partial reproduction in any form and by any electronic or mechanical means of the texts and/or pictures contained in this manual without the written authorization of the manufacturer is forbidden.

Treatments should not be performed on skin lesions.

If the package, the cable or the connector of the power supply show signs of wear or damage, replace it instantly.

The device should be connected to the mains by its power supply. Before starting the treatment, make sure that the power system specifications comply with the directives in force in your country. Make sure that the power supply will be easily unplugged.

The use of muscle stimulation programs referred to the treatment of urinary incontinence can be used exclusively for the treatment of urge, stress and mixed incontinence.

### Warnings before the use

Do not use this device simultaneously with other electronic devices, especially if they maintain vital functions. In case it is necessary to use the device nearby or on other devices, make sure it works properly, please refer to the chapter EMC accompanying documents.

- It is recommended to read carefully the entire operating manual before using the unit; keep carefully this operating manual.

- The device is capable of delivering current values exceeding 10mArms.

- Before each use always check the integrity of the device. This is a fundamental requirement for carrying out the therapy; do not use the device if the buttons or the cables are defective or malfunctioning.

- It should not be used for purposes other than transcutaneous neurostimulation.

- The device must be used with the transcutaneous neurostimulation electrodes suitable for this use.

- The device must be kept out of the reach of children.

- With its current, it can disturb ECG monitoring devices.

- It must not be used in a transthoracic mode as it could cause cardiac arrhythmia by superimposing its frequency to that of the heart. (Do not perform the treatment on the chest and the back simultaneously)

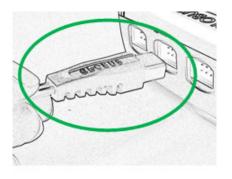
- A simultaneous connection of a patient to a high frequency electrosurgical device can cause burns near the electrodes of the stimulator and therefore the stimulator may be damaged.

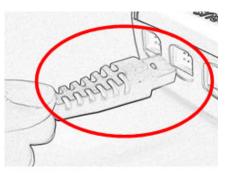
- Once you have turned the device on, make sure the display shows the software version and the device model: it means that the device is working and ready to be used;

If it doesn't, or the display does not show all the segments, turn it off and on again. If the problem persists, contact the service center and do not use the device.

- The sudden shutdown shortly after the starting indicates a low battery level. Recharge as reported in the section "HOW TO CHARGE THE BATTERIES".

#### How to connect the cables





OK

NO

In order to connect the cables to the device, plug the connectors into the intended inlets on the top of the unit (see picture). **Cables should be inserted with grooves downwards.** The inlets are placed exactly under the corresponding channels.

NOTE: for EMS and TENS currents use indifferently the 4 channels with colored

cables.

- NOTE: for Microcurrent programs use only channels 1 and 3 with gray cables.
- NOTE: For programs with currents for DENERVATED muscles (rectangular,

and trapezoidal currents), use only channels 1 and 3 with colored cables.

- NOTE: for programs with interferential currents use only channels 1 and 3 with colored cables.
- NOTE: for programs with ionophoresis currents use only channel 1 with gray cables.

#### Connection of the electrodes

Take the electrodes from the original packaging; all new electrodes have a sealed packaging. Ensure that the device is off. To start, connect the two plugs of the cables to the electrodes, then remove the electrodes from their place and put them on the skin. To place the electrodes correctly, see the images at the end of this manual.

After the use, place the electrodes back in their specific place. WARNING: do not unplug the electrodes if the device is operating.

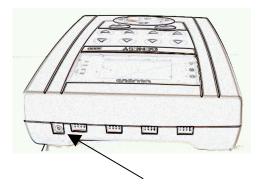
#### Battery

The device works both connected to the mains and with the use of rechargeable batteries.

The device is supplied with a set of rechargeable nickel-metal hydrate batteries (12V, 2Ah) with high performances and no memory effect.

The battery has an estimated life of 6 months in case it is not used. The number of cycles (discharge and recharge) depend on the type of stimulation and on the frequency treatments are executed. The device is supplied with charge indicator; it is advisable to recharge when it indicates <sup>1</sup>/<sub>4</sub>. In case after recharge the number of executable treatments is reduced, the battery must be replaced.

#### How to charge the batteries



Turn the electrostimulator off and disconnect the electrodes, then connect the electrostimulator to the power supply by inserting the plug in the appropriate inlet (see picture above). Do not use a power supply different from the one provided with the device. Contact an authorized service center to replace the set of batteries.

#### Safety precautions

While using the electrosimulator, some warnings should be followed:

- In the case of damaged cables, they must be replaced with original parts and not used anymore.

- Only use Globus marked electrodes.

- Great attention has to be paid when current densities exceed 2mA/cm<sup>2</sup> (effective value) for each electrode.

The device must be kept out of the reach of pets, as they could damage the device and contaminate the electrodes and other accessories with parasites.

- The cables of the electrostimulator should not be wrapped around people's neck to avoid any risk of strangulation and suffocation. - Keep out of the reach of children who may accidentally swallow small detachable parts of the device (for example the support feet).

- Mobile and fixed radio communication devices might affect the functioning of the electromedical device: see the tables attached to this manual. Please refer to the chapter EMC accompanying documents.

# Contraindications

The device should not be used in the following cases:

- -Stimulation of the urogenital apparatus, in case of extra-ureteral incontinence;
- -Stimulation of the urogenital apparatus, in case of incontinence due to evacuation disorders;
- -Stimulation of the urogenital apparatus, in case of chronic urinary retention, in the upper urinary tract
- -Stimulation of the pelvic floor in presence of a complete peripheral denervation;
- In case of actual or alleged tumour formation, consult the oncologist
- -Pains with unknown etiology.
- -Stimulation on areas with sores and dermatological diseases.
- -Stimulation on areas with acute traumas
- -Pregnancy;
- -Presence of severe cognitive deficiencies that do not permit the patient to communicate or perceive pain or discomfort;
- -People whose sensitivity to heath and/or pain is diminished due to surgery interventions, anesthesia, ionizing radiations treatments, diabetes, etc.;
- - Presence of severe pathologies on main organs
- - Presence of neurological diseases.

-Do not use the device on the following parts pf the body:

- -Eyes zone;
- Stimulation of the anterior neck (carotid sinus).
- -Brain region
- - Near body areas with metallic implants or infra-tissue metals (e.g. prostheses, osteosynthetic devices, coils, screws, plates), when using monophasic currents such as interferential and continuous currents (ionophoresis).
- In presence of pacemaker and active implantable medical devices.

-Patients suffering from a total/subtotal prolapsed uterus/vagina must be evaluated by a doctor and stimulated with extreme caution.

Patients with urinary tract infections should be treated for these symptoms before starting use the electrostimulator.

It is also recommended to use the device with caution in case of capillary fragility, as excessive stimulation may cause a further break of capillaries.

For those programs that consist in anal or vaginal stimulation, in addition to the general warnings, the following contraindications have to be considered:

- Presence of sexually transmitted diseases.
- Presence of total prolapsed uterus.
- Presence of urinary infections.
- Presence of severe or chronic dermatological diseases.
- Presence of ischemic tissues, wounds, skin or damaged or irritated mucosa, and/or in presence of infections.
- Presence of contraceptive vaginal ring.
- After an invasive or ablative surgical intervention, which has not been totally cured.
- Patients subject to bleedings or using anticoagulants.
- In case of a weak immune system due to an immunosuppressive disease or while using immunosuppressive medicines.
- Presence of overflow incontinence
- Presence of obliterated urethra.
- In case of atrophy of the involved orifice that may cause tissue injuries.

#### Side effects

Isolated cases of skin irritation or allergic reaction might occur in people with high skin sensitivity.

If during the treatment signs of tachycardia and extrasystole appear, suspend the treatment and contact your physician.

# **USER GUIDE OF THE DEVICE**

# For a correct use of the device, proceed as follows:

- connect the cables to the inlets on the unit;

- connect the electrodes to the specific connectors at the end of the cables;
- place the electrodes on the skin.

#### Start

υp

Hold the On/Off (OK) button down for about 3 seconds until a sound signal is heard.

The model name and software version will appear with a number on the lower right.

Depending on the model, different entries will appear. Use the P+ and P- buttons of the joypad to choose your function in the main menu:

Last 10
Program List
Favorites
Treatments
Programming
Advanced

#### Program List menu

When selecting the "Program list", the following areas are displayed depending on the model:

- SPORT
- FITNESS-PHYSICAL SHAPE
- AESTHETIC BEAUTY
- MEDICAL CURRENTS
  - MICROCURRENTS
  - DENERVATED
  - IONOPHORESIS
  - ANTALGIC PAIN
  - REHABILITATION

INTERFERENTIALS ELECTROTHERAPY

#### **Program selection**

- Area selection::

Use the P+ and P- buttons to select the desired area and press OK to confirm. Press the LEFT (Back) button to return to the previous screen.

- Program selection.
- Body part selection (where it is present)

#### How to start the program

When the program is selected, the display will show the following entries:

- Start;
- Electrode position;
- Save to Favorites (see Favorites Menu)
- Save to Treatments (see Treatments Menu)
- Continue with 2+2 (see 2+2 mode)

To start the program press Start and increase the intensity of the channels in the screen that follows.

#### How to increase and decrease intensity

To increase/decrease the intensity of single channels, press Up and Down on the corresponding channel.

Press P+ or P- to increase or decrease the intensity of all the channels.

#### Runtime function (how to change the working phase parameters)

After starting the program, the following parameters can be edited:

- Time
- Frequency
- Amplitude

Press Function to edit the parameters of the phase in progress: a new screen will appear and display the phase time.

Press P+/P- to edit the time.

Press Fn or wait for 5 seconds to confirm the new time settings.

Press LEFT/RIGHT and repeat the above-mentioned procedures to edit the other parameters.

#### Display during program execution

While the program is running, the screen displays the name of the program (at the top), the number of total phases and the phase in progress, the remaining time of the phase in progress and the type of the wave used (EMS, TEN, MICROC...). When performing an intermittent treatment, the screen displays the countdown indicator and the work and rest phases.

#### How to pause the program

To pause the program, press the "Ok" button on the joypad. Press OK again to return to the program.

At the start of every treatment or after the interruption of a protocol, the device restarts from a 0 intensity value.

#### How to stop the program

Press OK for three seconds to stop the program before its end.

#### How to skip a phase

Hold RIGHT down for 3" to pass on to the following phase before the conclusion of the phase in progress.

Hold LEFT for 3" to return to the previous phase.

#### "Last 10" Menu

The electrostimulator keeps track of the last 10 executed programs. In this way, they are available for a very simple and fast execution.

Recording takes place automatically at the end of the execution of a program. If the memory is full, the older program is automatically deleted.

When you turn the device on, select "Last 10" and confirm with OK.

With the P+ and P- keys of the joypad, select the program you want to run (if there is no program in this menu you will read "EMPTY").

After confirming the selection 3 entries will appear:

- a Start
- b Posit. placement (electrode placement)
- c Delete from the list

a - After selecting "Start", it is possible to choose whether to run the program in automatic or normal mode. Press OK to activate the Automatic mode. Press any Increase Intensity button to run the program in Normal mode.

The message AUTO appears on the display when the "automatic" function is activated.

Automatic function (AUTO STIM) Available only for EMS and TENS currents.

The "AUTO STIM" function allows to execute automatically a program that has already been executed, without having to set the intensity. Intensity values will be set automatically, restoring the values used during the latest execution of the same program. The "AUTO STIM" function can only be activated by the programs stored inside "Last 10" memory in the menu.

NOTE:

- To run a program in "AUTO STIM" mode, it is strictly necessary that the electrodes of each channel are placed in the same position and muscular group (or body part) as in the latest execution of the program. Intensity values are specific for each channel.

- If the "AUTO STIM" function is used, each user has to use the machine always with his/her USER code.

Press any intensity button to exit the "AUTO STIM" mode.

b - choose "Electrode placement" you will have a guide to the correct positioning of the electrodes.

For further information on the electrode position, see the illustrated guide at the end of this manual.

c - Select "Delete from the list" to remove the program from the "Last 10" list.

The "Last 10" memory refers to a specific user. The "USER SELECTION" (Multi-users) function allows the creation of a "Last 10" memory (up to 25 users plus the default user, defined as USER 0).

#### "Favorites" Menu

The "Favorites" menu allows you to save the most used programs on a special memory. In order to save a program, enter the "Program List" menu and choose the program you want to store. Before the execution, select "Save to Favorites" and confirm with OK.

The selected programs are easily available inside the "Favorites" menu.

NOTE: In Mode 2+2, it is not possible to store programs in the Favorite area.

### "Treatments" Menu

The "Treatments" menu (**Stim Lock**) allows the user to lock the device and ensure that only the treatments saved with the "Save to..." function in the screen-page before the execution of the program are performed.

This feature is conceived for the rental of the device to inexperienced users and/or patients who have to perform only certain protocols determined by the professionals.

#### Stim Lock function activation

Press and hold the buttons fn + --> (RIGHT button) for at least 3 seconds until the area where treatments have been saved After the Stim Lock is activated, the device will have a limited functionality.

#### Stim Lock function deactivation

Hold the fn + <-- (SX) buttons down for at least 3 sec. and in any case until the main menu appears.

NOTE: If you turn the device on and the main menu does not appear

check that the Stim Lock function is not on.

Try to deactivate it.

If the problem persists contact the customer care service.

#### "Programming" Menu

The electrostimulator offers the possibility of creating and modifying new programs. This makes the device flexible and adaptable to your needs.

From the "Programming" menu you can create new programs (when the message "EMPTY" appears) and perform those already customized. These can be modified at any time (see "Edit program").

#### How to create a new program

With P+ or P- buttons, select the spot where you want to create the program and confirm with OK.

#### How to insert the name of the program

Use the Left and Right buttons to select the letters and confirm with the OK button. In order to delete a letter select "Del". After inserting the name of the program select "Continue".

#### Setting of the parameters

STEP 1 Press "P+" or "P-" to select the stimulation type.

STEP 2 Press "P+" or "P-" to select the number of phases of the program.

STEP 3 After the number of phases is programmed, a series of screens will give the possibility of selecting the parameters. Use P+ and P- buttons to make your choice. The previously described steps are the same for all the programs.

If the program presents more phases, the next required phase will be automatically proposed at the end of the insertion of a phase.

#### N.B. The programmed stimulation types vary according to the model.

#### Editing or deleting a program

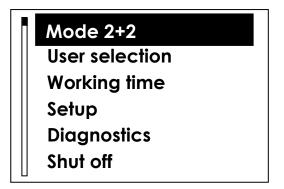
In the "Programming" menu you can edit or delete programs that you previously stored in memory.

Press "fn" + "P+" to edit and "fn" + "P-" to delete.

NOTE: it is not possible to program mixed multiphase programs (e.g. a EMS+TENS program).

# Advanced Menu

The advanced menu includes the following entries:



#### <u>Mode 2+2</u>

The device permits the simultaneous execution of two different programs (EMS or Tens), permitting the treatment of two patients or two muscular groups at once. How to set multiple treatments:

There are two options to run two programs simultaneously:

a) Select the "2+2 mode" from the "Advanced" menu;

b) From the Program list menu;

a) Select "Advanced - 2+2 mode" from the main menu and press OK to confirm.

Select the area and the name of the first program. At this point, it is possible to select the area and the name of the second program.

b) from the menu "Program list" choose the area and the desired program. At this point, select "Continue with 2+2" and choose the second program.

Note: During the execution of the 2+2 mode, the following screen will appear:

<sup>1</sup> ⁄ <sub>2</sub> Firming <sup>3</sup> ⁄ <sub>4</sub> Toning ma	ssage	
EMS 20 <sub>min</sub> ●	EMS •	20 <sub>min</sub>
SET INTENS	TY	

The program on the left side of the screen will work on channels 1 and 2, while the one on the right side on channels 3 and 4.

#### <u>User selection</u>

It allows to use the special menus ("Last 10", "Favorites") in a personalized way.

In order to gain access to favorite and "Last 10" programs, it will be sufficient to select one's USER. The programs stored in this area can be used only by that specific user.

NOTE: Every time the device is turned on, the last selected user will be displayed.

### Working time

It indicates the total time the device has been used for stimulation treatments.

### <u>Setup</u>

By selecting the Setup menu, the following screen will appear:

Lighting Time Contrast Auto Shut-Off Time Language Selection Sounds of Service Battery Management

#### • Function "Lighting Time"

Press P+ and P- to modify the backlight time in stand-by mode.

"Contrast" function

Press P+ and P- to modify the display contrast.

• "Auto shut off timer" function

It permits the user to choose the inactivity period after which the device automatically shuts down. Press P+ and P- to set the time in minutes.

#### • - "Language selection" function

Press P+ and P- to choose one of the 5 available languages. Confirm the selection with OK.

#### • "Service sounds" function

It allows to enable (YES) or disable (NO) the acoustical beeps the device emits.

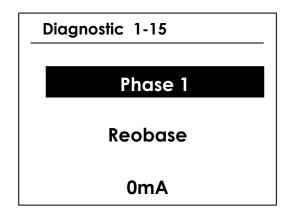
• "Battery Management" function (see page 21)

#### **Diagnostics**

The device offers a complete protocol that guides you to find the optimal parameters to stimulate a denervated muscle. Parameters can be easily defined and stored.

#### How to insert the name of the program

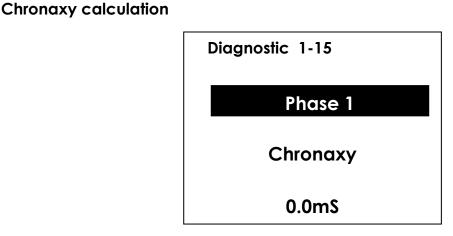
Use the Left and Right buttons to select the letters and confirm with the OK button. In order to delete a letter select "Del". After inserting the name of the program select "Continue".



#### **Rheobase calculation**

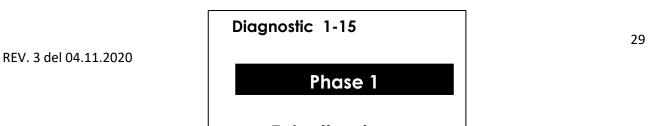
Press P+ to increase or P- to decrease intensity. When the first motor response occurs, the corresponding intensity value can be stored by pressing the OK button. This value corresponds to the rheobase, that is the minimum intensity value that allows to obtain excitability with a long duration pulse. Its only function is to allow the calculation of the chronaxy.

N.B. The absolute value of the rheobase depends on the position and size of the electrodes used; it establishes the contractile value of the muscle and its trophism. It is recommended to use small electrodes (diameter from 32 to 50 mm maximum).



# The device automatically selects an intensity value which is twice the rheobase. The pulse width is automatically set to a minimum value. The operator must gradually increase the pulse width value. When the first motor response occurs, the pulse width must be confirmed by the therapist with the OK button.





After storing the chronaxy value, you are asked if you want to set the pulse slope value, thus changing the shape of the pulse from rectangular (used by default) to trapezoidal-triangular. Set the number of sessions to be programmed using P + and P-, then press the OK button. Proceed by increasing the intensity value until the stimulation is reached. It is possible to further modify the slope value and consequently also the intensity value in the setting screens.

Reobase	40mA
Chronaxy 1.10	ms
ame	
ate Ramp up	Intensity
<b>0</b> °	40 mA

NOTE: the programs determined by the diagnostics are saved in the PROGRAMMING area from which they can subsequently be run.

#### Outcome

Chronaxy less than 1 millisecond: The muscle is normally innervated.

Chronaxy between 1 and 10 milliseconds: This moderate increase in chronaxy reveals a low rate of denervation that does not necessarily require preventive treatment, given the limited number of denervated fibers.

Chronaxy between 10 and 20 milliseconds: a high increase in chronaxy and the presence of spontaneous activity reveals that a certain number of motor units are inhibited while others are functional. The muscle is normally innervated. The treatment consists in stimulating the denervated fibers selectively, possibly eliminating the participation of healthy fibers. This is made possible thanks to the use of progressively sloping, trapezoidal or triangular currents.

Chronaxy over 20 milliseconds: characterized by the absence of voluntary activity. A chronaxy from 20 to 40 milliseconds reveals complete denervation, that is, a total interruption of nerve conduction. The treatment is carried out with long-lasting rectangular currents (100 or 300ms).

# Program List Sport

Demo
Capillarization
Warm-up
Pre-competition warm-up
Active recovery
Maximum strength
Endurance strength
Explosive strength
Aerobic endurance
Reactivity
Post-competition recovery
Decontracting
Hypertrophy
Total 53

NOTE: some programs are divided by area of the body CE0476 does not refer to non-medical treatments.

# Fitness-Physical shape program list

Firming
Bio-Pulse Firming
Sculpting
Bio-Pulse Sculpting
Toning
Mass building
Body sculpting
Definition
Jogging
Anaerobic fitness
Aerobic fitness
Cramp prevention
Total 29

NOTE: some programs are divided by area of the body CE0476 does not refer to non-medical treatments.

# **Beauty-Aesthetics program list**

Drainage
Lipolysis
Toning massage
Skin tone improvement
Connective massage
Post-pregnancy drainage
Post-pregnancy lipolysis
Post-pregnancy firming
Total 16

CE0476 does not refer to non-medical treatments.

# Medical currents - Microcurrents program list

The following programs are medical

#### NOTES ON THE USE OF MICROCURRENT PROGRAMS

This paragraph refers to the use of microcurrent programs

Microcurrent programs differ from standard EMS and TENS programs as follows:

- While conventional electrostimulation (e.g. TENS) uses current in the milliampere range, microcurrent electrostimulation uses currents in the microampere range that are not perceptible by humans. **Therefore, feeling no sensation is perfectly normal.** 

- When running a Microcurrent program, **use exclusively the special gray cables and connect them to the outlets of channels 1 and 3 only.** If the cables are not connected or they are of the wrong type, the program will not start. Check the cables and the connections.

- Microcurrent programs have a fix pre-established intensity value, therefore it is not necessary to set it.

The device automatically brings the intensity to the correct level after a program is confirmed. This value should not be modified during the session.

- Microcurrent programs cannot be run in the "2+2 mode" with multiple treatments.

If one tries to select a Microcurrent program in "2+2 mode", the device will emit an error tone.

If, upon suggestion of the therapist, you wish to modify the working protocol by altering the intensity, press and hold the Up or down button for 3 seconds.

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia S.p.A. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.



Program List - Medical Currents - Denervated

The following programs are medical

Triangular 1
Triangular 2
Triangular 3
Trapezoidal 1
Trapezoidal 2
Trapezoidal 3
Rectangular 1
Rectangular 2
Rectangular 3
Total 9

Use an electromyograph to determine the level of denervation and the relative program.

In absence of this sophisticated tool, the empirical method is used, this means that the treatment starts with a triangular treatment (i.g if the denervation is partial) and if no muscle response occurs, also trapezoidal and rectangular treatments are executed.

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia S.p.A. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

# Program list - Medical currents - Ionophoresis

The following programs are medical

Ionophoresis	
Total 1	

Current intensity should be regulated so as to be barely perceptible.

Therapy medicament MUST NEVER BE APPLIED DIRECTLY ON THE SKIN, but always on the absorbing surface of the electrode which corresponds to the polarity of the medicament, while the absorbing surface of the other electrode will have to be dampened with slightly salted water in order to facilitate current circulation.

- When using ionophoresis programs, use only the special light/dark gray cable and connect it only to the channel 1 output.

- IONOPHORESIS programs cannot be run in "2+2 mode" with multiple treatments.

- IONOPHORESIS programs are saved in the "Last 10" menu, but cannot be executed in "AUTO STIM" mode.

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia S.p.A. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

### Medical currents Program List - Antalgic pain (Tens)

The following programs are medical

Endorphinic tens
Muscle injuries
Sciatica
Cervical pain
Epicondylitis
Carpal tunnel
Hip osteoarthritis
Knee pain
Menstrual pain
High-freq.ant.Tens
Conventional Antalgic Tens
Modulated antalgic tens
Nerve compression
Muscle pain
Chronic pain
Post surgical pain
S. H. syndrome
Low Frequency Antalgic Tens
Spinal osteoarthritis
Spinal osteoporosis
Ankle osteoarthritis
Muscle tendon injury pain
Knee osteoarthritis
Chronic lumbago
Trapezius pain
Fracture pain
Ac.pain ing.hernia
Whiplash
Osteoarthritis
Rotator cuff tendinitis
Bursitis-tendinitis
Post-surgical pain
Spinal compression pain
Total 33

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia S.p.A. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

# Program list Medical currents – Rehabilitation

The following programs are medical

Swollen ankles
Atrophy
Functional recovery
Recovery after ACL surgery
Ankle re-education
Leg re-education
Muscular spasms
Shoulder subluxat.
Vastus medialis reinforcement
Lower limb hemiplegia
Upper limb hemiplegia
Total 11

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia S.p.A. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

When finished with the rehabilitation protocol, in the Rehabilitation section there are the following programs:

Agonist-Antagonist	Х
Muscle reinforcement	Х
Motor point pen	Х

# Program List Incontinence (in the rehabilitation area)

The following programs are medical

Mixed incontinence
Stress incontinence
URGE Incontinence
Total 3

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia S.p.A. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

# **Interferentials Program List**

The following programs are medical

Acute lumbago
Cervical Pain
Pain verteb. fract.
Chronic lumbago
Frozen shoulder
Post surgical pain
Fibromyalgia
Knee osteoarthritis
Edema
Total 9

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia S.p.A. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

# Program list electrotherapy

The program list of electrotherapy permits to choose the current parameters personally, in order to ensure that the specialist have the maximum precision in the currents he/she uses.

The program list of Electrotherapy NEMS includes 192 parameter combinations.

	-	
NEMS	Frequency	
	2	
NEMS 4s-8s	5	
NEMS 4s-12s	10	
NEMS 4s-20s	20	
NEMS 8s-8s	50	
NEMS 8s-12s	80	
NEMS 8s-20s	100	
	120	
PROGRAM LIST 192		

The program list of Electrotherapy NEMS includes 44 parameter combinations.

	Time	Frequency
		1
Kotz 2500 Hz	5s/5s	5
	4s/12s	10
	10s/10s	30
	10s/20s	50
	10s/30s	80
		100
Total Programs	2	14

# **GENERAL NOTES ON ELECTRODE POSITIONING**

Correct electrode positioning and size choice are fundamental to assure the effectiveness of electrostimulation.

To choose the size of the electrodes and their positioning it is necessary to refer to the images at the end of this manual. Information is also available on our website www.globuscorporation.com. For all the programs that cause significant muscle contraction (e.g. strength, hypertrophy, toning and firming programs) it is fundamental to place the electrode on the muscle **motor point**, which is the most sensitive to stimulation. If the electrode is not positioned exactly on the motor point, the contraction could be small and/or annoying. In this case it is necessary to shift the positive electrode of a few millimeters to feel an effective and comfortable muscle contraction.

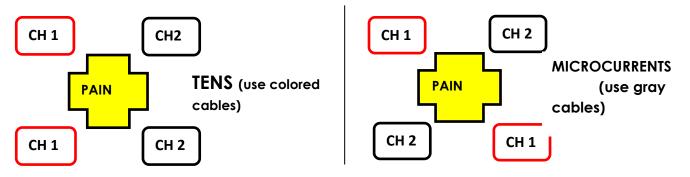
#### Body position during stimulation

Body position during electrostimulation depends on the body part involved and on the type of program that is being carried out.

During the execution of treatments with high intensities, we suggest blocking the limbs in order to work isometrically. For instance, if you want to treat quadriceps with a strength program, we suggest to carry out the treatment in a sit position and block the feet, in order to avoid involuntary leg extension during the contraction. For all the programs that do not imply high intensity (massages, decontracting, drainage...) the body position is not important, as long as it is comfortable.

#### Electrode positioning for Tens and Microcurrent programs

In the following pages of this manual you can find the images with the correct electrode positioning for tens and microcurrent treatments. If the localization of your pain type is not included among the images, you can place the electrodes by forming a "square" on the aching area. Here you have an example.



#### Indications for the use of ionophoresis

This program uses a low-intensity and continuous current (between 5 and 10 mA) that helps the absorption of the active ingredients of a drug in a specific area of the body. It is often required that a drug is administered directly on the area that needs to be healed, avoiding an oral or intravenous administration. With ionophoresis it is possible to administrate a drug through transcutaneous penetration directly on the body area that needs to be treated.

The drug must be prepared in ionic form and must have an electric charge. The principle on which ionophoresis is that the continuous current flows through skin from one electrode to the other (from anode to cathode) consequentially transporting the electrically charged iones that are inside the treated body area.

In practice, sponges soaked in a solution containing the active ingredient are used, bearing in mind that if it has a negative charge, it must be applied to the negative electrode and vice versa. The current will carry the active principle inside the tissues, because the ions of the active principle itself will migrate towards the opposite pole until the product is completely absorbed. The kit with sponges and electrodes for ionophoresis is an extra accessory that can be purchased separately.

The intensity value is adjustable from a minimum of 0 mA to a maximum of 10 mA. To ensure safety, the maximum intensity, calculated with the smallest ionophoresis electrodes (50 x 50 mm), is 0.40 mA per cm<sup>2</sup> of electrode.

DENSITY = Current displayed in mA / Electrode area in cm<sup>2</sup>

# Indications for the application

- The manufacturer declines the responsibility of the prescribing physician for the choice of the drug to be used with ionophoresis. For this purpose, in this user manual the manufacturer provides the data for a correct definition of the protocol and the drug that has to be used.
- Before using ionophoresis, therefore, it is mandatory to contact the prescribing doctor.
- Both sponges in the ionophoresis kit must be wetted with distilled water or physiological solution, then insert the silicone electrodes inside the sponges and connect the cables.
- The drug used for the therapy should never be applied directly on the skin but to the absorbent surface of the electrode corresponding to the polarity of the drug itself. In fact, it is very important to consider the positive or negative charge sign of the active ingredient of the drug, which must be applied correctly: the drug must be placed on the electrode with the same charge sign as the active ingredient.
- Place the two electrodes on the area that must be treated, at a distance of about 10-20 cm and fix them with the elastic band.
- Gradually increase the intensity until the patient feels a slight tingling.
- Once the program is finished, turn the device off, and disconnect the electrodes. Clean the sponges and bands following the instructions on the drug leaflet. If not indicated, it is however recommended to wash the sponges and elastic bands very well, with plenty of hot water and soap, so that the next time there are no traces of the drug.

# Indications for the treatment with incontinence programs

The use of muscle stimulation programs referred to the treatment of urinary incontinence can be used exclusively for the treatment of urge, stress and mixed incontinence.

These three programs are indicated for the reinforcement of the pelvic floor, that often cause incontinence. The program must be chosen after a diagnostic of the type of incontinence (urge, stress and mixed). Urological applications entail the use of vaginal or anal probes for the specific intended use, which must be covered by the CE MDD certification, in compliance with the directive 93/42/CEE. Such probes must be bipolar and equipped with a 2 mm female connector for 2 mm male cables. Such probes are available in stores with the following reference codes:

**REF G1188** Single-patient vaginal probe **REF G0757** Single-patient anal probe.

#### Warnings

Since these applications have a medical intended use, they must be carried out upon previous medical authorization.

#### Use

- To use the probes correctly, follow the instructions provided by the manufacturer or the physician.
- Then connect the stimulation cable to the probe: the connector of the stimulation cable with the + symbol must be connected to the red connector of the probe. The symbol must be connected to the black connector of the probe.



- Connect the cable to the device.
- For the vaginal stimulation, lie flat supine with bended knee and opened legs. To use the anal probe, lie on one side in lateral decubitus position
- Insert the probe in the vagina or anus using, if necessary, some water-based gel
- Choose and start the incontinence program
- Gradually increase the intensity until perceiving a muscular contraction.

Once the program is finished, turn the device off, extract the probe and disconnect the connection cables. Clean the accessory and put it in a clean bag.

# **ELECTRODE POSITION**



Biceps brachii



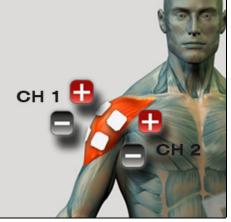
Triceps brachii



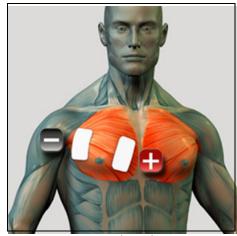
Flexor carpi



Extensor carpi



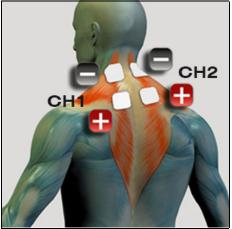
Deltoid



Pectoral



Pectoral

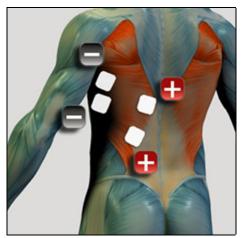


Trapezius

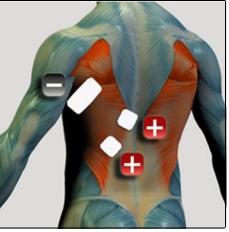


Trapezius

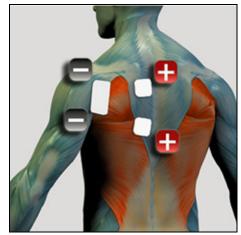
# **ELECTRODE POSITION**



Latissimus dorsi



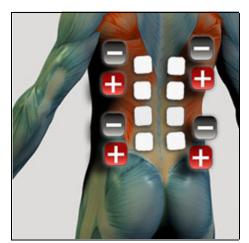
Latissimus dorsi



Infraspinatus



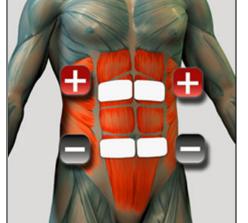
Lower back



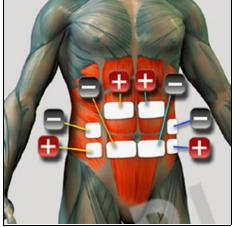
Lower back/Back



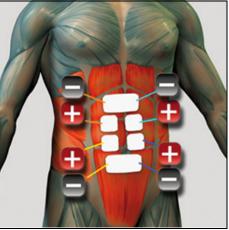
Abdominals



Abdominals

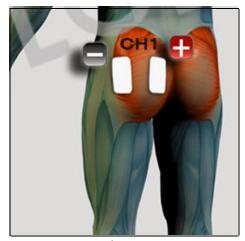


Abdominals

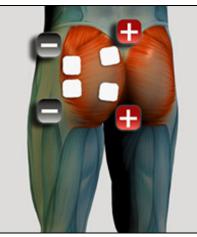


Rectus abdominis

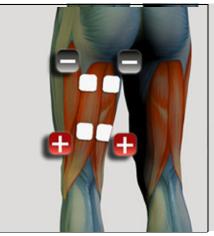
# **ELECTRODE POSITION**



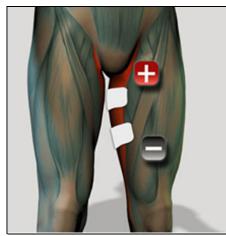
Gluteus



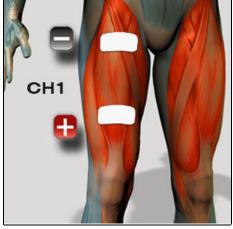
Gluteus



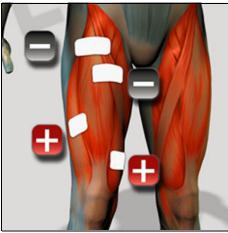
**Biceps femoris** 



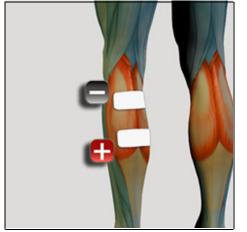
Adductors



**Rectus femoris** 



Quadriceps



Gastrocnemius

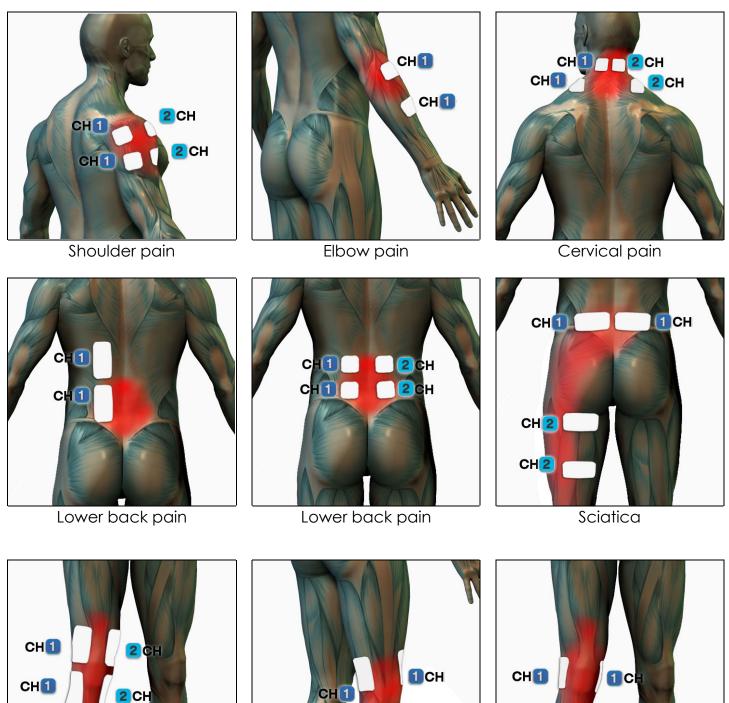


Gastrocnemius



Tibialis anterior

# **ELECTRODE POSITION (TENS)**



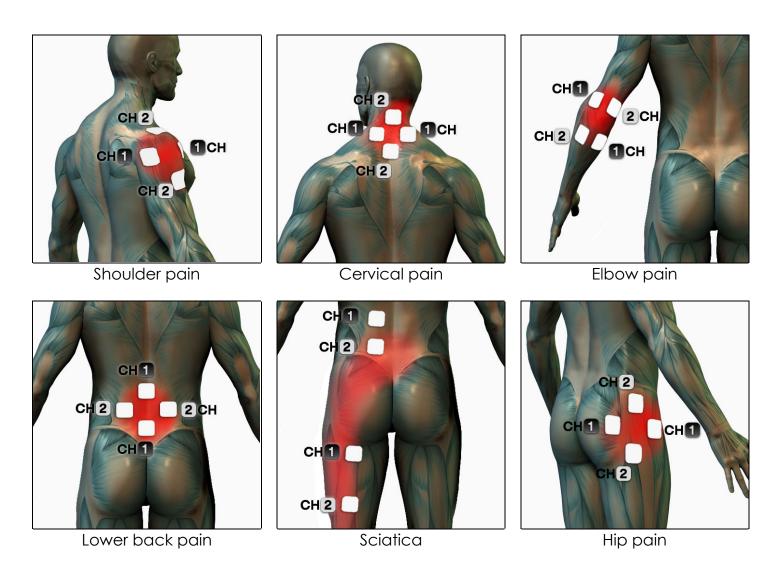


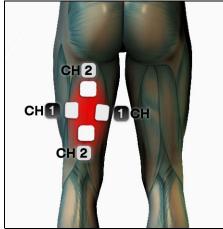


# Knee pain

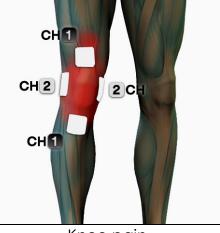


# **MICROCURRENT ELECTRODE POSITIONING**

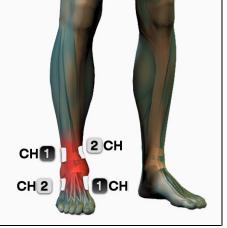




Muscle pain (electrodes must be placed on the aching area)



Knee pain



Ankle pain

# **ACTION PRINCIPLES**

# Muscular electrostimulation

Electrostimulation is a technique that, by means of electric pulses that act on the muscle motor points (motoneurons), causes a muscular contraction similar to voluntary contraction.

The majority of human muscles are striated or voluntary, with approximately 200 muscles on each side of the body. (about 400 on the whole)

# The physiology of muscular contraction

The skeletal muscle performs its functions through contraction. When a movement is made, the motor center of the brain sends an electric signal to the muscle to be contracted.

When the electric signal reaches the muscle, the motor plaque of the muscle surface produces the depolarization of the muscle membrane and the release of CA++ ions inside it. The Ca++ ions, interacting with the actin and myosin molecules, activate the contraction mechanism which leads to the shortening of the muscle.

The energy required to contract the muscle is provided by adenosine triphosphate (ATP) and supported by a recharging system based on aerobic and anaerobic mechanisms using carbohydrates and fats. In other words, electrostimulation is not a direct source of energy, but it acts as a tool triggering muscle contraction.

The same principle is activated when muscle contraction is generated by EMS, which act as a natural impulse transmitted by the motor nervous system. At the end of the contraction, the muscle relaxes and returns to its original state.

# Isotonic and isometric contraction

An isotonic contraction occurs when, during a movement, the muscles overcome external resistance, thus shortening and leading to a constant state of tension in the tendon heads. An isometric contraction occurs instead when external resistance impedes the movement; thus muscle contraction does not generate the muscle shortening but an intensity increase on its tendons. Isometric stimulation is normally used in electrostimulation because it permits a more powerful and efficient contraction.

# The distribution of the different fiber types in the muscle

The relationship between the two main categories (type I and type II) can vary in a considerable way.

There are muscular groups that are typically made up of type I fibers, like the soleus, and muscles which only have type II fibers, like the orbicular muscle; however, the majority of human body muscles is composed of a combination of the two types. Studies on the distribution of fibers in the muscle have highlighted the close relationship between the (tonic or phasic) motoneuron and the functional features of the fibers it innervates; moreover, they have proved that a specific motor action (particularly in sports) can lead to a functional adaptation of fibers and change their metabolic features.

Motor unit type	Contraction type	Contraction frequency
Tonic ST	slow contraction I	0 - 50 Hz
Phasic FT	fast contraction II	50 - 70 Hz
Phasic FTb	fast contraction II b	80 - 120 Hz

# **Stimulation intensity**

The intensity value required to trigger contraction depends on patients, electrode placement, adipose tissue, perspiration, possible hairs on the treatment surface etc. Therefore, the same current intensity may give different sensations to different people, in different days or body sides. It is advisable to regulate the intensity during the same session to contrast accommodation, in order to obtain the same contraction.

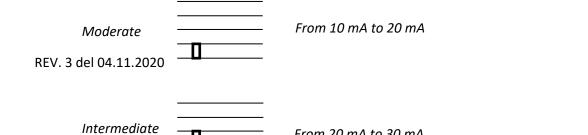
The current intensity for the different phases is suggested with an approximate value and can be modified on the basis of individual sensations.

- Moderate: the muscle does not tire, even during long treatment. The contraction is agreeable and tolerable. First level of the intensity graph.

- Intermediate: the muscle is visibly contracted but the stimulation does not trigger the joint movement. Second level of the intensity graph.

- High: the muscle is contracted noticeably. The muscle contraction would extend or bend the limb if not blocked. Third level in the intensity graph.

- Maximal: the muscle is contracted maximally. This is an intense treatment that should be performed only after many applications.



In treatment description, recommended intensity levels are indicated. N.B. Recommended current levels are just an indication.

NOTE: It is not necessary to set the intensity value (in mA) in Microcurrent programs, since it has already been set for all the phases.

#### Open circuit

This device includes a controlling device of power emissions. If the operator increases the intensity level above 10 mA and the circuit is open(cables are not connected to the device and electrodes are not applied to the skin), the electrostimulator immediately resets the intensity to 0 mA.

Therefore, before starting a program, make sure that the cables are connected to the device and that the electrodes are placed on the area to be treated and that they are not worn, as this could decrease their conduction capacity. NOTE: Use Microcurrent programs only on channels 1 and 3 with the gray cables supplied. If the cables are not connected or they are of the wrong type, the program will not start. Check the cables and the connections.

#### Tens

Transcutaneous Electrical Nerve Stimulation (TENS) is a selective stimulation of the large fibers of the peripheral nerves favoring the closing of the gate entrance for the pain pulses and increasing the release of endorphinic substances, reducing in this way the pain intensity. Therefore TENS is particularly indicated to treat the severe and chronic pain caused by the main musculoskeletal disorders.

TENS currents reduce pain thanks to the following factors:

- a. Gate control theory
- b. Endorphin secretion
- c. Different sedative effects related to frequency

# Gate theory

If the electrical signals that lead to the brain information about pain are stopped, also the perception of pain is eliminated. For instance, if we hit our head against an object, the first thing we do is massaging the traumatized area. In this way we stimulate the receptors of touch and pressure. TENS in continuous mode and frequency modulation can be used to generate signals similar to those of touch and pressure. If their intensity is enough, their priority is so high that it prevails on the pain signals. Once the priority is obtained, the gate related to the sensory signals is opened and the pain gate is closed, thus impeding the passage of these signals to the brain.

#### Endorphin secretion

When a nervous signal proceeds from the pain area to the brain, it spreads through a chain of connections joined together called synapses. The synapse can be seen as the space between the end of a nerve and the start of another. When an electric signal reaches the end of a nerve, it produces substances called neurotransmitters that pass through the synapse and activate the start of the next nerve. The process is repeated until the signal reaches the brain. The opioids involved in pain reduction have the task of sliding in the synapse space and impeding the neurotransmitter propagation. In this way a chemical block of pain signals is obtained. Endorphins are opioids naturally produced by the body to tackle pain and they can act both on the marrow and on the brain, proving to be effective analgesics. Tens can increase the natural production of endorphins; therefore they decrease the perception of pain .

#### Different effects related to frequency

Higher frequencies determine immediate, short-lasting antalgic effects, whereas lower frequencies determine gradual, long-lasting effects.

# Microcurrents

Unlike conventional electrostimulation, microcurrent electrostimulation uses currents with an intensity included between 10 and 500  $\mu$ A (microamperes, that is a millionth of an ampere). Several studies have proved that microampere currents actually increase ATP synthesis.

MENS therapy usually has two different phases: the first aims at reducing the pain sensation perceived by the patient, while the second promotes protein and ATP synthesis, accelerating tissue repairing processes. The treatment duration is usually included between 15 and 30 minutes as for the first phase and between 5 and 10 minutes as for the second phase. MENS are an interesting instrumental therapy that can be used in a lot of pathologies; moreover, the use of MENS combined with other instrumental therapies such as laser and/or TENS can lead to excellent clinic results, which are otherwise unlikely to be reached.

### lonophoresis

lonophoresis is a form of electrotherapy through which pharmacological substances are transmitted inside the tissues thanks to a unidirectional continuous electric current.

lonophoresis is based on the ionic dissociation capacity of some medicinal substances, which have very low molecular weight, after they are dissolved in water.

It is crucial to know if the active part of the medicine, after being dissociated in a ionic form, has positive or negative charge, with the aim of placing it correctly according to the direction of the electric flow. The ions of the medicinal substance are transmitted inside the organism through cutaneous areas that oppose a low resistance to the current, reaching the cellular membranes that are thereby electrically modified.

# Denervated

The stimulation of denervated muscles differs from the stimulation of healthy muscles, since the activation of the muscle fibers requires particular currents.

In the presence of a traumatic lesion of the peripheral nerves, measuring the chronaxies allows the determination of a low, partial or total denervation. The aim of an excitomotory treatment is to maintain muscle trophism and to limit its sclerosis during the reinnervation process, which may last several months and reduce muscle efficiency. The effectiveness of the treatment depends on the correct setting of the stimulation parameters, which as to be clearly defined for each patient and adapted as the treatment proceeds.

#### **Rectangular current**

Rectangular currents are characterized by one single rectangular pulse, varying rapidly from zero to the highest set intensity, from a contraction duration equal to the duration of the pulse, from a pause corresponding to the muscle recovery time. Rectangular pulses cause muscle contraction, the pulse duration determines a selective contraction of denervated fibers; a pulse average value equal to zero (alternate polarity) avoids the ionization of the skin. Rectangular pulses are mainly used on totally denervated muscles. The program varies according to the pulse duration and the rest time.

#### Triangular current

Triangular currents reach the highest intensity value with a linear ramp up, which, if combined with sufficiently long pulses, determine an efficient contraction response of the denervated fibers (controlled by injured muscles) without stimulating adjacent innervated fibers. Being an excitomotor current, the triangular pulse contracting denervated fibers will be followed by a pause where the current value is equal to zero. Pulse polarity is alternate to avoid the ionization of the skin. Triangular currents are used to stimulate totally or partially denervated muscles, thanks to the accommodation capacity of nerve fibers to the slow intensity increase and the absence of ailment in the patient. Fiber selective stimulation does not involve innervated fibers, which has been observed in the use of alternate rectangular currents, because of the pulse rapid increase The program varies depending on pulse range and rest duration.

#### Trapezoidal current

Trapezoidal currents are mainly used on partially denervated muscles. The program varies according to the pulse duration and the rest time.

#### Interferential

Interferential current is a sinusoidal alternating current with medium frequency (2500 Hz - 4000 Hz - 10000 Hz), modulated in amplitude, characterized by a high ability to penetrate tissues and excellent tolerability even by particularly sensitive patients. The analgesic action of bipolar interferential, with modulation frequency between 0 and 200 Hz, is traced back to the gate control mechanism, to the stimulation of the inhibitory mechanism, to the peripheral block of pain transmission, to the removal of algogenic substances from the affected region, as for the TENS current. By changing the modulation frequency used, it is possible to benefit from an excitomotor effect, which contributes, by activating the "muscle pump", to the return of venous flow.

They are called interferentials because they are formed and interfere with tissues in the points where

# Kotz

It's a sinusoidal medium-frequency current (2500 Hz), modulated in packets of 10ms followed by pauses of the same duration, in which the packets are modulated to generate a muscular CONTRACTION phase and a rest phase.

Like all the medium-frequency currents, it can be easily penetrated and sometimes it's more preferable than low-frequency currents (biphasic and faradic rectangular) to stimulate the deeper muscles.

# MAINTENANCE AND CLEANING

# Device

- In case of actual or alleged malfunctioning, do not tamper with the device and do not try to repair it by yourself.

- Do neither intervene on the device nor open it. Only specialized and authorized centers can repair it.

- Avoid violent impacts that may damage the device and cause malfunctioning, also not immediately detectable.

- Use this device in a dry and open environment. Do not wrap the device.

- Clean the device only by using disinfectant with sodium hypochlorite or quaternary ammonium salt (percentage: 0.2-0.3%) diluted with distilled water. After cleaning/disinfecting the device, dry it perfectly with a clean cloth.

- It is recommended to clean/disinfect the parts after every use, unless otherwise indicated.

- Always use the device with clean hands.

- It is recommended to use the device in a clean environment to avoid contamination with dust and dirt.

- It is recommended to use the device in a ventilated, well-aired space.

# Battery

# Battery management

The device has a menu that allows to see the status of the battery charge, if the device has one. The values displayed in this menu enable the manufacturer and/or the authorized help center to check the status of the battery charge.

# Accessories

# Use and storage of the electrodes and the cables

In case of damaged cables or electrodes, these should be replaced and not used anymore.

Before placing the electrodes on the skin, we suggest to clean it accurately. After using the multi-purpose single patient and/or single-use electrodes, they must be stored using their plastic film and placed in a clean closed plastic bag.

Electrodes should not touch each other nor overlie one over the other.

Once the package has been opened, the electrodes can be used for 25-30 applications.

Electrodes must always be replaced if they are not perfectly in contact with the skin.

If using non self-adhesive electrodes it is suggested to clean their surface with proper cleansers that respect the requirements described in the manual. Use the electrodes with clean hands.

The electrodes in their bag should be stored in an environment that respects the requirements described in the manual.

At the end of the treatment, unplug the cables from the connectors and clean them carefully with proper cleansers that respect the requirements described in the manual.

After cleaning and drying them, fold them up and place them in the plastic bags supplied along with the cables.

# WARRANTY

The device is guaranteed to the first user for twenty four (24) months from the purchase date against material or manufacturing faults, twelve (12) months if the device is used for professional purposes, provided that it is used properly and maintained under normal operating conditions.

Warranty coverage is limited in the following cases:

- six (6) months for supplied accessories subject to wear, such as batteries, battery chargers, power supply units, cables, G-Trode handpiece.

- ninety (90) days for the media containing software such as, for example, CD-ROMs, memory cards, etc.

- The warranty does not the cover "consumer" accessories and materials such as the electrodes, etc.

The warranty is valid and enforceable in the country where the product was purchased. In the event that the product is purchased in an EU country, the warranty is valid in all the member states.

In order to take advantage of the warranty service, the user must comply with the following warranty clauses:

1. Products have to be sent for repairs by and at the expenses of the Customer in their original packages and with full original equipment.

2. The warranty of the product is subject to the exhibition of a fiscal document (sales receipt or invoice) attesting the purchase date of the product.

3. The repair work shall have no effect on the original expiry date of the warranty and shall neither renew nor extend it.

4. If no defect is found, when it comes to carrying out the repair work, the costs of check time will be charged in any case.

5. The warranty becomes void if the flaw has been caused by: impacts, falls, misuse of the product, use of non-original power supply units or external chargers, accidental events, alteration, replacement/detachment of the warranty seals and/or tampering. Moreover, the warranty does not cover damages caused during transportation when unsuitable packages are used (see point 1).

6. The warranty does not cover the inability to use the product, other incidental or consequential costs or other expenses incurred by the purchaser.

**NOTE:** Before returning the device for repairs, we recommend reading carefully the user instructions in the manual and visiting the Globus website.

If you have to return the product for repair, please contact your dealer or the Globus customer service.

#### Essential performance

PERFORMANCE	CONDITION	RISK	ACCEPTED EVENT
Electrostimulation.	External disturbance (Burst).	Display information no longer readable.	The machine must stop the stimulation.
			The machine must maintain the stimulation and accept the commands.
	Lack of internal power supply.	Interruption of the treatment.	The machine must signal the battery exhaustion and the interruption of the treatment.
	Lack of external power supply.	Interruption of the treatment.	The device, if equipped with a battery, must continue the treatment signaling that operation is carry out in battery mode.
e Ti m d So tł	Detachment of an electrode.	Unpleasant stimulation or painful electric shock in case of reconnection of the electrode.	The device must constantly monitor the current on each active channel set over 9 mA. In case the detected current is below a certain threshold, the machine must rest the current of the channel.
	The cable for microcurrents is not detected.	Dangerous stimulation.	The device must report an error relating to the electrodes and prevent the program from starting.
	Setting of a current that is too high in case of microcurrents.	Dangerous stimulation.	The device must derate the voltage boost stage to prevent emitting a current beyond the maximum value.
			The device must not start the microcurrent treatment if it does not detect the hardware derating of the voltage booster stage.
Loading of the programs from the memory.	Error in the data from the memory.	Execution of an incorrect program.	The machine must check the correctness of the data of the programs. In case an error is detected, the device must restart.
Change of settings. Setting error.	Setting data memory error.	Operation error.	The device must check the correctness of the settings data and in case of errors it must load the default settings present in copy in the memory and must indicate on the display that the reset has been carried out.
		Display information no longer readable.	The device must check the contrast value. If it is out of range, the device must reset the value to the default one.
Battery charge.	Battery overheating.	Damaging of the device, display information no longer readable, explosion, fire.	The device must monitor the temperature of the battery, if a certain threshold is exceeded, the battery charging must be interrupted.

In compliance with:

EN 60601-1: 2006 + A1: 2013 EN 60601-1-2: 2015 EN 60601-2-10: 2015

Warning: radiofrequency communication devices (including accessories like antennas or antenna cables) must be used at least 3 meters away from every part (including cables and accessories) of the device. Otherwise performance can be affected.



DOMINO S.R.L. - Via Vittorio Veneto, 52 - 31013 Codognè (TV) - Tel. (+39) 0438.7933

globuscorporation.com You Tube in F