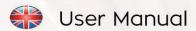


# **ELECTROSTIMULATORS**



PREMIUM 400





# **DEAR CUSTOMER**

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



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# **TECHNICAL FEATURES**

#### **Device**

Size: 160x99x35.4 mm

Weight: 404 g

Case: in Food Grade ABS

Protection level: IP20 + IP02

#### Storage and transport conditions

Storage and transportation temperature: from -10°C to 45°C

Max. relative humidity: 30% - 75%

The values indicate the limits allowed if the product or its accessories are not in the original package.

#### **Use conditions**

Temperature: from 0°C to 35°C Max. relative humidity: from 15% to 93%

Atmospheric pressure: from 700 hPa to 1060 hPa

#### **Technical features of the currents**

EMS and TENS:

Channels available: Channels 1-2-3-4

Constant current: Yes

Intensity: 0-120 mA with 1000 Ohm load

Waveform: Rectangular, biphasic, symmetrical,

compensated

Working frequency: 0.3-150 Hz
Recovery frequency: 0.3-150 Hz
Pulse amplitude: 50-450 µs

Working time: from 1 to 30 seconds
Recovery time: from 0 to 1 minute

Frequency mod. range: continuous variation from 1 to 150 Hz

Min. modulation time: 3 seconds

Amplitude modulation range: continuous variation from 50 to 450 µs

Microcurrents:

Channels available: Channels 1-3

Constant current: Yes

Min.frequency: 5Hz Max.frequency: 200Hz

Min. Intensity:  $0 \mu A/1000 \text{ Ohm Step } 10 \mu A$ 

Max. Intensity: 800  $\mu$ A/1000 Ohm

Amplitude value: included between 1 and 250 µseconds

**Ionophoresis:** 

Channels available: Channel 1

Constant current: Yes

Min. Intensity: 0 mA/1000 Ohm

Max. Intensity: 10 mA/1000 Ohm step 0.1 mA/1000 Ohm

Min. time: 1 minute
Max. time: 99 minutes

Charger

Brand: FLO

model: DKT-088-0200-EU

Input: 100-240V~ 50-60Hz 0, 2A

Output: + 8.8V=== 0.2A

**Battery** 

Battery pack: Ni-MH 7,2 V 1,8 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 after sales service is guaranteed for 5 years. We suggest having a check of the device every 2 years for the maintenance and to ensure the safety. The numbers of treatments depend on the battery charge.

#### The risk class of the device is IIb.

The intended use of the device is to provide:

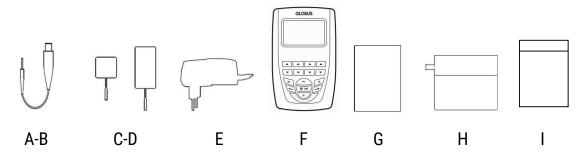
- analgesic electrotherapy through stimulation of the peripheral nervous system;
- muscle electrostimulation in order to reduce atrophy and spasticity and increase muscle strength.

The electrostimulators are designed to be used in the following operating environments:

- domestic environment;
- clinics:
- physiotherapy centers;
- rehabilitation centers;
- general pain treatments;
- beauty and sport purposes (CE0476 does not refer to non-medical treatments);

The use of this device is permitted to the patient (appropriately informed about the use conditions of the device) and to medical staff. The user of these devices must be able to understand and want and be at least 18 years old.

# **EQUIPMENT**



The electrostimulator is supplied complete of cables and electrodes to use: therefore, opening the package, it is necessary to check that the basic equipment is complete. If some elements should be missing, contact immediately the authorized retailer where you purchased the product.

Control carefully the integrity of the device and its electrodes.

- A. 4 colored electrode connection cables (for EMS and TENS treatments)
- B. 2 gray cables for electrode connection (for MICROCURRENT and IONOFORESIS treatments)
- C. 4 reusable self-adhesive electrode (50 x 50 mm)
- D. 4 reusable self-adhesive electrode (50 x 90 mm)
- E. Charger
- F. Device
- G. User manual
- H. Carrying bag
- I. IP02 waterproof case

#### **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 G0465: Electrodes Myotrode Plus (50x90 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 used with the optional accessories listed below (it is possible to see their features in the website <a href="www.globuscorporation.com">www.globuscorporation.com</a>). In order to purchase these accessories, please contact your dealer.

REF	Name	Description
G1188	Vaginal probe	Probe for the treatment of incontinence and for the reinforcement and/or relaxation of the pelvic floor.
G0757	Anal probe	Probe for the treatment of incontinence and for the reinforcement and/or 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.
G0488	Fast Body kit	fast band + fast pad
G0890	Medium ionophoresis electrode	Carbon electrode + pouch 50x50 mm
G0885	Big ionophoresis electrode	Carbon electrode + pouch 60x85 mm
G0439	Kit 2 splitting cables	This accessory is used to split the cables in order to use more electrodes at the same time.

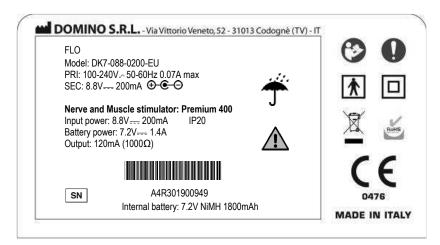
# LABELLING AND SYMBOLS



	It refers to the manufacturer
$\triangle$	Warning The device emits current values over 10 mA or10V
<del>*</del>	Keep the device dry
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.
<b>*</b>	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 Romesica	It indicates that the product has been designed in compliance with the directive 2011/65/EEC
	It informs the operator that s/he must read the manual before using the device.
0	It informs the client of the compulsory conduct
1	It indicates the ideal temperature for the storage and transportation of the product.
IP20	It indicates water protection

PREMIUM 400		
Model	It indicates the power supply model	
PRI	Input electric features of the power supply	
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 with external power supply.	
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.	
<b>\$••</b>	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	

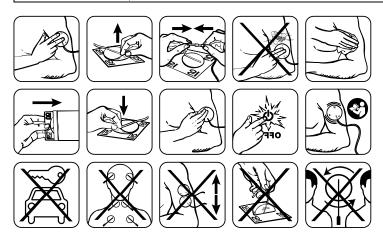
#### **Device**



**SN** The first 4 digits of the serial number indicate the week and year of manufacture of the device you purchased (for example, if the code is \*\*\* 2319 \*\*\*\*\*, it means that the device was manufactured in week 23 of 2019).

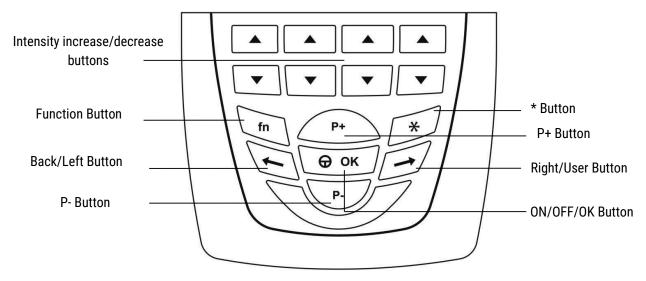
#### **Electrodes**

Z	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
30.6°F + 27°C 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

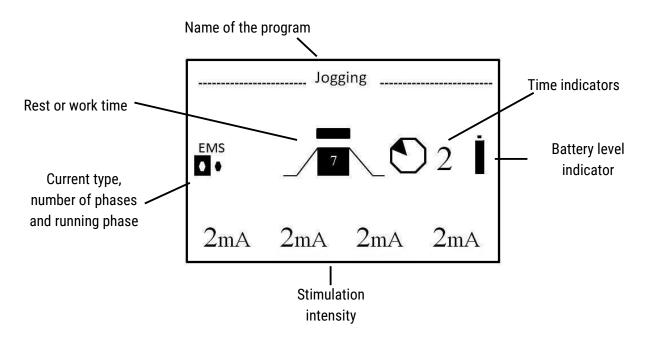


NOTE: when the 3" message appears, it means that holding the button down for 3 seconds activates the function.

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.

PREMIUM 400		
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)	
Intensity button	It increases/decreases the stimulation intensity of the corresponding channel.	

# **Display and interface**



# **INFORMATION SIGNALS**

#### **Compliance**

Certifications: CE MDD certificate.

The sound and acoustic signals are in compliance with the 60601-1-8 directive.

#### Meaning of the signal "Electrode error"

If one or more cables are not duly connected to the mains, or if cables for microcurrent are erroneously used to run an EMS program, the following signal will appear on the display: "Electrodes error".

# 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 with its power supply; before doing so, make sure that the power system complies 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



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 microcurrents and handpiece for face use channel 1 or 3.

NOTE: For ionophoresis, use channel 1 only 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 equipped with a nickel-metal hydride rechargeable battery pack (7.2V, 1.8Ah), which has a high performance 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 ¼. In case after recharge the number of executable treatments is reduced, the battery must be replaced.

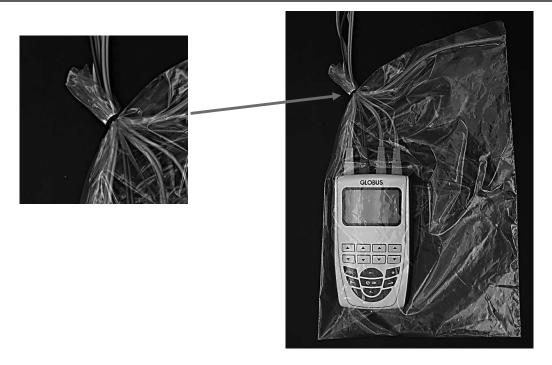
#### How to charge the batteries



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.

#### Use of the waterproof case

To ensure the IP 02 waterproof level in home use, put the device into the waterproof case included in the equipment. Then pressure-close the zip and let the cables come out of the upper corner of the case. Use a twist tie to seal the closure on the corner. Complete the insertion as in the picture below.



#### **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/cm² (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 tumor 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**

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 up

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:



#### "Program List" menu

When selecting "Program List", the following areas, according to the model, are shown:

- SPORT
- SPECIAL SPORTS
- FITNESS-PHYSICAL SHAPE
- BEAUTY-AESTETHICS
- MEDICAL CURRENTS
  - MICROCURRENTS
  - PAIN-ANTALGIC
  - IONOPHORESIS
  - REHABILITATION
- ACTION NOW
- SERIAL SEQUENTIAL STIMULATION

#### **Program selection**

- Area selection:

With the P+ and P- buttons of the keyboard, move the cursor on the desired area. Press OK to confirm.

Press the left (Back) button to return to the previous screen.

- Program selection.
- Body part selection (when available)

## How to start a program

Once you have selected a program, the following entries will appear:

- Start;
- Electrode placementi;
- Save in Favorites (see "Favorites" menu);
- Save in Treatments (see "Treatments" menu);
- Continue with 2+2 (see 2+2 mode).

To start the program, confirm with Start and in the following screen increase the channel intensity.

#### Increase/decrease intensity

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

To increase/decrease the intensity of all channels simultaneously, press the P+ or P-buttons of the keyboard.

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

Once a program has started, it is possible to modify:

- time
- frequency
- amplitude

To modify the parameters of the phase in progress, press the Function button. A new screen appears and the phase time is highlighted.

Modify the time pressing the P+ and P- buttons of the keyboard.

The new time will be automatically confirmed after 5 seconds or by pressing the FN button.

Move to the other parameters that you want to modify by pressing the LEFT/RIGHT buttons and repeat the above mentioned process.

#### Visualization during a program execution

While a treatment is executing, the display shows the program name (top), the indicator of the phase number and of the phase in progress, the remaining time of the phase in progress and the type of the wave used (EMS, TEN, MICROC...) For programs with intermittent stimulation, the working and the rest phase are graphically represented together with the time countdown.

#### How to pause a program

To pause a program, press the OK button. Press OK again to return to the program. The intensity indicators will start from zero every time you start or stop a treatment.

#### How to stop a program

If you need to stop a program before its end, turn off the instrument by pressing and holding the OK button for about 3 seconds.

# How to skip a phase

In order to pass to a next phase before the end of the one in progress, press and hold the RIGHT button for 3 seconds.

To return to the previous phase, press the left (back) button for 3 seconds.

#### "Last 10" menu

The electrostimulator stores the last 10 executed programs, so that these are available for rapid and easy execution.

The storage occurs automatically at the end of each program. When the memory is full, older programs are automatically deleted.

When the device turns on, select "Last 10" and then confirm with OK.

Select the program you wish to execute by pressing the P+ and P- buttons.

(If no programs are stored on memory, the message EMPTY appears).

After confirming, three entries are displayed:

- a. Start
- b. Electrode placement
- c. Delete from the list
- a. It is possible to execute the selected program by placing the cursor on "Start"
- b. Placing the cursor on "Electrode placement", a brief guide for correct electrode placement is displayed.

For further information on the electrode placement, see the picture included in the end of this manual.

c. Placing the cursor on "Delete from the list", the selected program will be no longer present in the "Last 10 executed programs" area.

The "Last 10" programs memory refers to a specific user. Thanks to the USER SELECTION (multi-user) function, different users (up to 10, plus default user, called USER 0) can have their own program memory of "Last 10.

#### "Favorites" menu

This menu enables the user to save the most used programs in a specific memory, up to 15 per user. To save a program, choose the program you want to save from the "Program List" menu. Before execution, select "Save in Favorites" and confirm with OK. The selected programs can be easily executed from the "Favorites" menu.

NOTE: In Mode 2+2, it is not possible to store favorite programs.

#### "Treatments" menu

The "Treatments" menu (**Stim lock**) enables the user to lock the device in order to permit only the use of the programs that have been saved with the special function "Save in..." in the screen previous to the execution of the program.

This function is especially thought for the rent of the unit to inexpert users and/or to patients that have to carry out only some special programs that have been chosen by the specialist.

#### Activation of the STIM LOCK function

Press and hold the buttons fn and --> (RIGHT button) for at least 3 seconds until the area where the treatments have been saved appears. After the activation of the STIM LOCK function, the unit will have limited functions.

#### Deactivation of the STIM LOCK function

Press and hold the fn and <-- buttons (LEFT button) for at least 3 seconds until the main menu appears.

NOTE: If the main menu does not appear, when the unit has been turned on, verify that the Stim lock function is not activated.

Try to deactivate it.

If the problem persists, contact the customer service.

# "Programming" menu

The Electrostimulator offers the possibility to create/ modify new programs.

This makes the device highly flexible and adaptable to all users' requirements.

From the "Programming" menu it is possible to create new programs (when the message EMPTY appears) and to execute already personalized programs. These programs can be modified at any time (see the section "How to modify a program" below).

The programs created with this function are the same for all USERS and cannot be stored in the "Last 10" menu nor in the "Favorites" menu.

#### How to create a new program

Use the P+ and P- buttons to select a number (from 1 to 10) for the program you wish to create and confirm with OK.

#### Program name insertion

To name the new program, use the LEFT and RIGHT buttons to select letters and confirm with OK. To delete a letter, move the cursor on "Delete". After inserting the program name, select "Continue".

# Parameters setting

STEP 1. Press P+ and P- buttons to select the type of stimulation desired.

STEP 2. Press P+ and P- buttons to select the program phase number.

STEP 3. After setting the phase number of which the program is composed, different screens will appear where it is possible to select the desired parameters. Use P+ and P-to carry out the selection.

The procedure executed until now is the same for every type of program you wish to create.

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

NOTE: The programmed stimulation types vary according to the model.

#### How to modify or delete a program

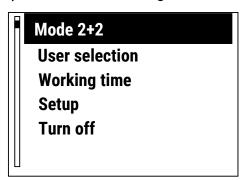
Inside the "Programming" menu, it is possible to modify or delete the programs previously stored.

Press and hold "fn" + P+" buttons to modify and "fn" + "P-" to delete.

NOTE: it is not possible to set mixed multi-phase programs. (e.g. EMS+TENS program).

#### "Advanced" menu

The advanced menu is composed of the following entries:



#### Mode 2+2

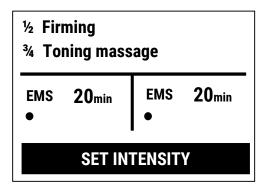
The device permits to execute two different programs (Ems or Tens) at the same time, permitting the simultaneously treatment of two patients or two muscular groups. How to set multiple treatments

To execute simultaneously two different programs, there are two possibilities:

- a. From the advanced menu selecting "Mode 2+2"\*
- b. From the "Program list" menu;\*\*
- \* From the main menu, select "Advanced -- Mode 2+2" and confirm with OK. Select the area and the name of the first program. Now, it is possible to select the name and the area of the second program.

\*\* From the Program list" menu select the area and the desired program. Now select "Continue with 2+2" and select the second program.

NOTE: During the Mode 2+2 the following screen will appear:



The program on the left works on channels 1 and 2, while the program on the right works on channels 3 and 4.

#### **User Selection**

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

To access to the favorite programs and to "Last 10" programs, the user should select his/her own user. Only that specific user can use the programs stored in the "Favorites" memory.

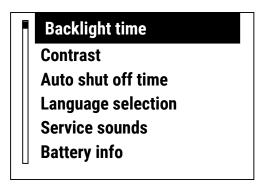
NOTE: Every time the device has been turned on, the last user will be displayed.

#### Working time

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

#### <u>Setup</u>

By selecting setup, the following screen will appear:



#### "Backlight time" function

It permits to modify with the P+ and P- buttons the duration of the backlight during the stand-by phases.

#### "Contrast" function

It permits to modify with the P+ and P- buttons the contrast level in the display.

#### • "Auto shut off time" function

It permits to set with the P+ and P- buttons, a period of time (in minutes) after which the device, if not used, automatically turns off.

#### • "Language selection" function

It permits to choose among 5 different languages for the navigation using the P+ and P- buttons. Confirm the selection with OK.

#### • "Service sounds" function

It permits to enable (ON) or disable (OFF) the acoustic tones emitted by the unit.

• "Battery info" function (see p. 20)

# **PROGRAM LIST**

# **Sport Program List**

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

NOTE: some programs are divided according to body areas.

CE0476 does not refer to non-medical treatments.

# **Special Sports program List**

cross country skiing	
Running	
Nartial arts	
ennis	
occer	
like-riding	
OTAL 44	

NOTE: some programs are divided according to body areas.

CE0476 does not refer to non-medical treatments.

# **Fitness-Physical Shape Program List**

rming
io-Pulse firming
culpting
io-Pulse sculpting
oning
ass Building
ody sculpting
efinition
ogging
naerobic fitness
erobic fitness
ramp prevention
OTAL 58

NOTE: some programs are divided according to body areas.

CE0476 does not refer to non-medical treatments.

# **Beauthy-Aestethics Program List**

Drainage	
Bio-pulse drainage	
Lipolysis	
Toning massage	
Connective massage	

# Swollen arms Face capillaries Lifting effect Skin tone improvement Post-pregnancy drainage Post-pregnancy lipolysis Post-pregnancy firming Breast firming Breast sculpting TOTAL 36

NOTE: some programs are divided according to body areas.

CE0476 does not refer to non-medical treatments.

# **Medical currents - Microcurrents Program List**

The following programs are medical

Epicondylitis
Scapulohumeral periarthritis
Muscle restoration
Contusion
Edema
Skin ulcer
Sciatica
Lumbago
Brachial neuralgia
Acute pain
Articular pain
Stiff neck
Whiplash
Cervical spondylosis
Shoulder sprain
Carpal tunnel
Knee sprain
Osteoarthritis
Ankle sprain
Achilles tendon inflamation
Patellar tendon inflammation

Rotator cuff inflammation	
Tendon inflammation	
TOTAL 23	

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 93/42/CEE directive for medical devices. The certification covers clinical applications.

#### NOTES ON THE USE OF MICROCURRENT PROGRAMS

This paragraph refers to the use of microcurrent programs.

The microcurrent programs differ from normal TENS and EMS programs as follows:

- While conventional electrostimulation (e.g. TENS) uses current in the milliamperes range, microcurrent electrostimulation uses currents in the microampere range that are imperceptible by humans. During Microcurrents programs, it is normal that the user does not discern any stimulation.
- When running a Microcurrents program, use exclusively the special gray cables connected to the outlets of channels 1 and 3. If the cables are not connected or are of the wrong type, it will not be possible to start the program. Check the connections and the cables.
- The Microcurrents programs have prefixed intensity levels, therefore it is not necessary to set them. When a Microcurrent program is activated, the electrostimulator automatically brings the intensity to the correct level. This value should not be altered during the execution of the program.
- The Microcurrents programs cannot be run in the "2+2 mode" with multiple treatments. If one tries to select a Microcurrents program in "2+2 mode", the electrostimulator will emit an error tone.

If, according to your therapist, you wish to modify the treatment protocol altering the intensity, press and hold the UP and DOWN button for 3 seconds.

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

The following programs are medical

Menstrual pain	
Modulated antalgic Tens	
Scapulohumeral syndrome	
Endorphinic Tens	
Chronic pain	
Muscle pain	
Chronic lumbago	

PREMIUM 400		
Cervical pain		
Bursitis-tendinitis		
Osteoarthritis		
Knee pain		
Conventional antalgic Tens		
Total 12		

DDEMILIM AND

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 93/42/CEE directive for medical devices. The certification covers clinical applications.

#### **Medical currents-Rehabilitation Program List**

The following programs are medical

Quadriceps atrophy
Recovery after ACL surgery
Shoulder subluxation
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 93/42/CEE directive for medical devices. The certification covers clinical applications.

# Incontinence program list (inside 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  $n^{\circ}$ . 0476 according to 93/42/CEE directive for medical devices. The certification covers clinical applications.

#### Maintenance of the probe electrode

For cleaning, sterilization and disinfection, refer to the manufacturer's instructions.

#### Medical currents - Ionophoresis Program list

The following programs are medical

Ionophoresis	
TOTAL 1	

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 93/42/CEE directive for medical devices. The certification covers clinical applications.

The home user can use ionophoresis treatments only after consulting a specialist who will prescribe treatment medicines and indications.

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.

#### **Action Now Program list**

Action Now programs are normal EMS programs, with the only difference that each single action will start only after pressing \* button. The Action Now programs are particularly useful to link and synchronize the electric stimulation with a voluntary action.

This program is suggested mostly in sport filed, for athletic preparation. It enables to activate the muscular contraction through an external control managed by an operator. In this way it is possible to link the stimulation to the voluntary contraction to obtain a greater recruitment of the muscular fibers and an important coordinating effect.

#### **OPERATING MODE:**

Contraction will start after pressing \* button. To interrupt contraction before contraction time is over, it is enough to press again \* button. In this case the program will cut the rest period and will place itself at the beginning of the ramp of the next stimulation, waiting for the user to press \* button in order to start contraction.

The following programs are not medical.

Action Now program list includes 7 parameter combinations.

	PREMIUM 400			
Program name	Hz	Ramp-Up time	Contraction time	
Action 0,2 - 1 s		0,2	1	
Action 0,5-1s		0,5	1	
Action 1 - 1 s	50	1	1	
Action 2 - 1 s		2	1	
Action 3 - 2 s		3	2	
Action 4 - 2 s		4	2	
Action 2 - 6 s		2	6	
Total 7 programs				

CE0476 does not refer to non-medical treatments.

### "3S" Serial Sequential Stimulation Program List

The "3S" programs are characterized by an activation delay of the channels 3 and 4 compared with the channels 1 and 2. The Serial Sequential Stimulation permits to stimulate the musculature in kinetic chain thanks to the differentiated activation times of the muscular groups involved.

In aesthetic field, the 3S programs allow to create a real sequential drainage: the sequential contraction of the different muscular groups produces a deep pressure wave in the musculature involved that causes the interstitial fluid drainage and it favors the return of the venous blood to the heart.

#### **OPERATING MODE:**

The operation of these programs is exactly the same as any other EMS programs, with the only difference that a delay in contraction start between the channels will be noticed. The following programs are not medical.

The 3S program list includes 18 parameter combinations.

Name	Hz	Delay time
SerSeqStim 0,5 sec		0,5
SerSeqStim 1 sec	30	1
SerSeqStim 2 sec		2
SerSeqStim 3 sec	50	3
SerSeqStim 4 sec		4
SerSeqStim serial	80	11
	Totale 18 programm	i

"Delay time" refers to the delay seconds that the next pulse needs to start. CE0476 does not refer to non-medical treatments.

# **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 websitewww.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**

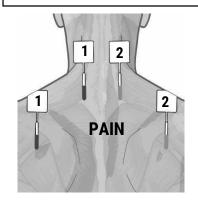
Body position during elctrostimulation depends on the body part involved and on the type of program that is being carried out.

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.

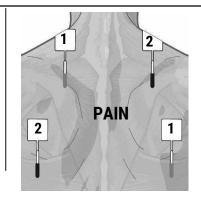
For all the programs that do not imply high intensity (massages, decontracting, drainage...) the body position is not important, as long as it is comfortable.

#### 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.



TENS (use colored cables)



MICRO CURRENT (use
gray cables)

#### 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:

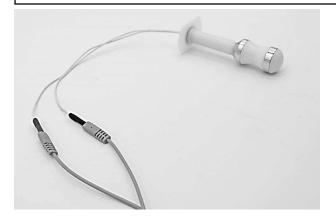
**REF G1188** Single-patient vaginal probe **REF G0757** Single-patient anal probe.

# **Warnings**

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

#### <u>Use</u>

- 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.

#### 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.

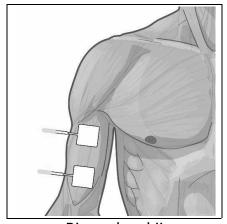
To ensure safety, the maximum intensity, calculated with the smallest ionophoresis electrodes ( $50 \times 50 \text{ mm}$ ), is 0.40 mA per cm<sup>2</sup> of electrode.

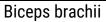
DENSITY = Current displayed in mA / Electrode area in cm<sup>2</sup>

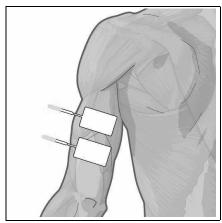
### Indications for the application:

- 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.

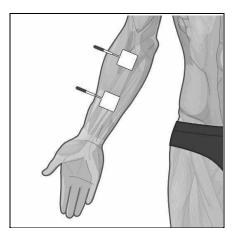
## **ELECTRODE POSITION**



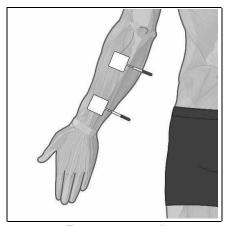




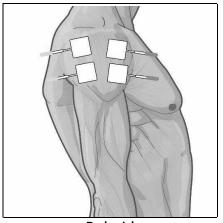
Triceps brachii



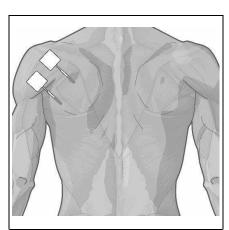
Flexor carpi



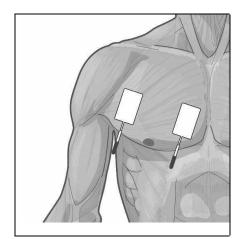
Extensor carpi



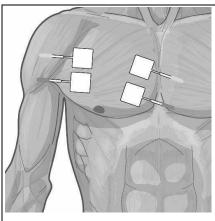
Deltoid



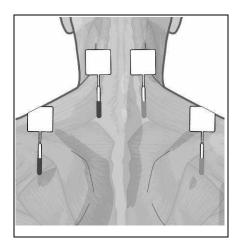
Posterior deltoid



Pectoral

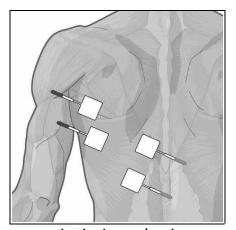


Pectoral

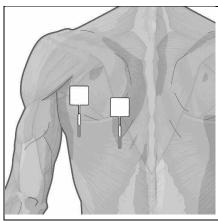


Trapezius

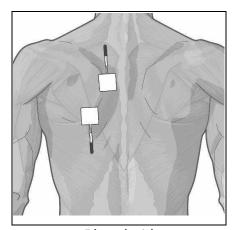
## **ELECTRODE POSITION**



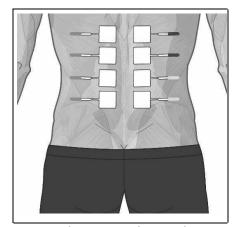
Latissimus dorsi



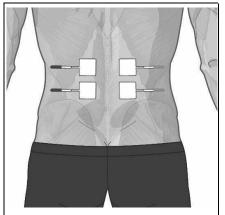
Infraspinatus



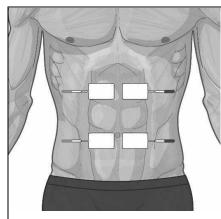
Rhomboid



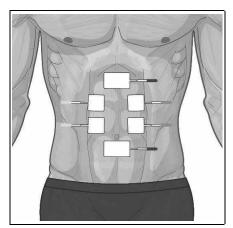
Lumbar/Dorsal muscles



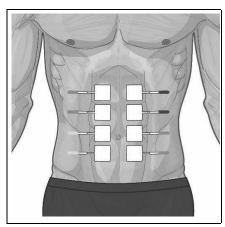
Lumbar muscles



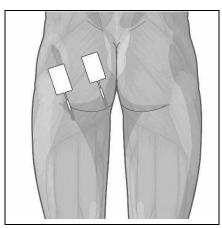
Abdominals



Rectus abdominis

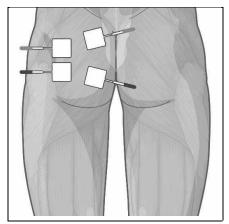


Rectus abdominis

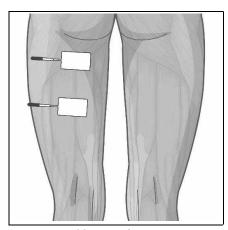


Gluteus

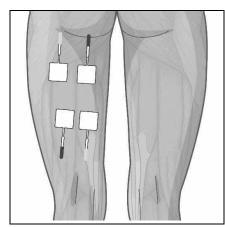
## **ELECTRODE POSITION**



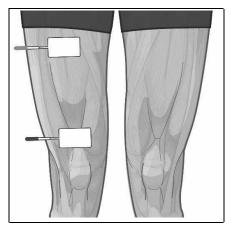




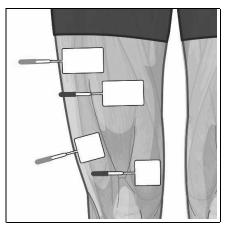
Hamstrings



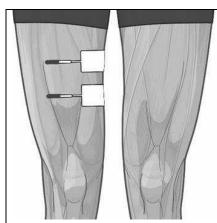
Hamstrings



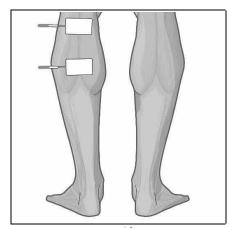
Quadriceps



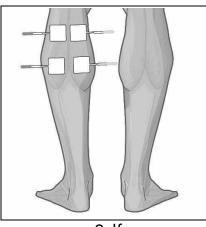
Quadriceps



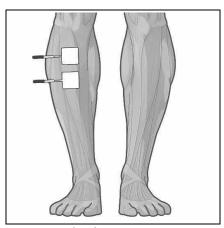
Adductors



Calf

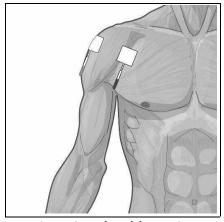


Calf

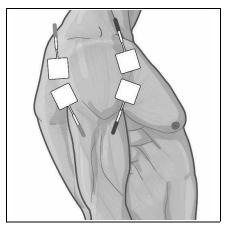


Tibialis anterior

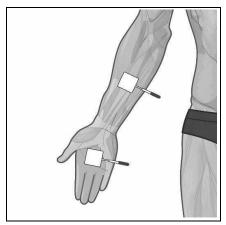
# **ELECTRODE POSITION (TENS)**



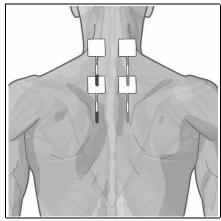
Anterior shoulder pain



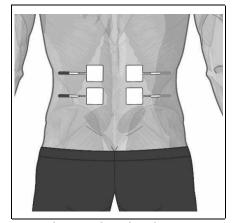
Shoulder pain



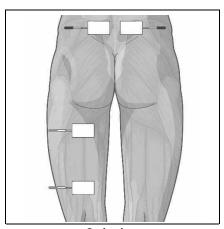
Carpal tunnel



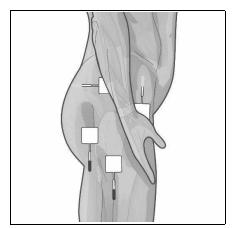
Neck pain/Whiplash



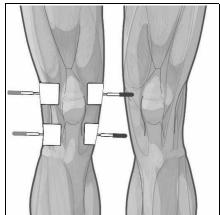
Chronic low back pain



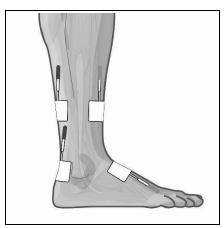
Sciatica



Coxarthrosis

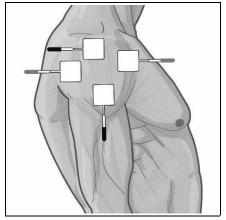


Gonarthrosis/Knee pain

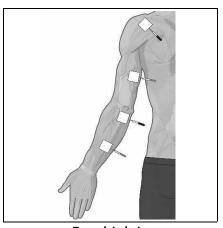


Ankle joint arthrosis

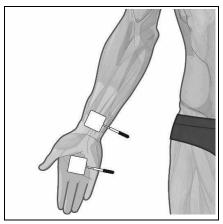
## **MICROCURRENT ELECTRODE POSITIONING**



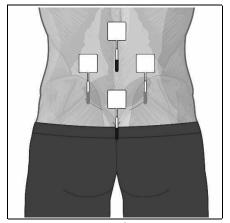
Shoulder dislocation



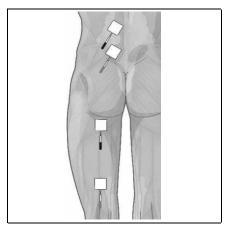
Brachialgia



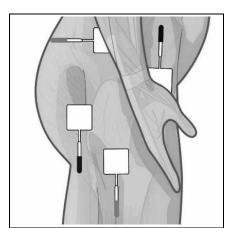
Carpal Tunnel



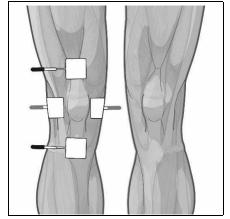
Low Back Pain



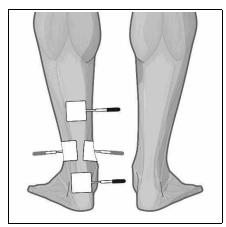
Sciatica



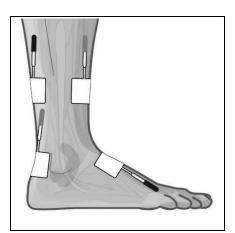
Hip pain



**Knee Osteoarthritis** 



Achilles Tendinopathy



Sprained ankle

## **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.

## <u>Isotonic and isometric contraction</u>

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.

Moderate	From10 mA to 20 mA	
Intermediate	From 20 mA to 30 mA	
High	Above 30 mA	
Maximal	On the verge of the tolerance limit, always under the threshold of pain.	

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 µA (microampere, which 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 many 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.

## **Ionophoresis**

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.

## 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**

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

If the cables or the electrodes are damaged, they 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 non self-adhesive electrodes are used, we suggest 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 a period of twenty-four (24) months from the date of purchase against defects in materials or of the manufacturing, twelve (12) months if the user uses the device 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, 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...
- No warranty for extendable accessories and materials such as, for example, 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 any country of the European Community, the warranty is still valid in all its countries.

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

- 1. The products, and all accessories, to be repaired must be sent by and at the expenses of the customer in their original packages.
- 2. The product's warranty is subject to the production of a fiscal document (fiscal receipt, receipted bill or sale invoice), attesting the product's purchase date.
- 3. The repair work shall have no effect on the original warranty expiry date and shall neither renew nor extend it.
- 4. If, during the repair work, no defects are found, the costs related to inspection times shall in any case be charged.
- 5. The warranty becomes void where the fault has been caused by: impacts, falls, erroneous or improper use of the product, use of non-original power supply unit or charger, accidental events, alteration, replacement/detachment of the warranty seals and/or tampering with the product. The warranty does not cover damages caused during transportation when unsuitable packages are used.
- 6. The warranty does not cover the inability to use the product, other incidental or consequent costs or other expenses incurred by the purchaser.

**NOTE:** Before returning the device for repairs, we recommend to read carefully the user instructions contained in the manual and visit Globus website.

In case you need to return your product for assistance, contact your dealer or contact Globus Service.

## **Frequently Asked Questions**

#### What kind of electrodes should be used for electrostimulation?

Use self-adhesive electrodes, which are practical and improve the quality of stimulation. If used with care, they will last for 25-30 applications. The electrodes should be replaced when they have no longer a good connection with the skin.

#### Where should the electrodes be placed?

In the back of this manual, there is a comprehensive electrode placement guide (it is not necessary to respect the polarities indicated). You can follow these instructions. To verify the correct placement of the electrodes, use the special Find Motor Point Pen program or follow this empirical method: place the electrodes as indicated in the pictures in the back of this manual; start the stimulation; with your hand, move the electrode by sliding it along the muscle without removing it from the skin. You will notice a change in contraction according to the different positions. Once you locate the point where the stimulation is greatest, decrease the channel intensity to zero (0,0 mA), replace the electrode and increase gradually the intensity.

#### Use of Y cables. This permits to use more electrodes on the same channel.

This, permits, for instance, to stimulate vastus medialis and vastus lateralis of the quadriceps with one single channel. They are not recommended for medical applications.

## Does the power decrease by using Y cables?

The power intensity for each channel does not vary. However, when Y cables are used to split one single channel in two, the current is distributed on a wider muscle area, therefore contraction will be less pronounced. Increase the intensity to obtain the same contraction level.

#### Can electrostimulation hurt me?

It is very unlikely that electrostimulation damages muscles. In this case it is important to increase intensity gradually while observing the muscle behavior and avoiding to keep the limb completely outstretched. In case of doubt, please contact a specialist.

## Is it possible to use the electrostimulator during menstruation cycle?

Electrostimulation may interfere in some way with menstruation, causing anticipation, delay, accentuation or reduction of the cycle; however, these effects are subjective and highly variable. It is recommended to avoid treatments in the abdominal zone during menstruation cycle and immediately before or after it.

#### Is it possible to use the electrostimulator during lactation?

Until now, no collateral effects regarding lactation have been observed. Nonetheless, during lactation, it is recommended not to stimulate the thoracic region.

# Are dermatological diseases (e.g. psoriasis, urticaria) contraindications for electrostimulation?

Yes, do not treat areas affected by dermatological diseases.

#### When are the first results visible?

Aesthetic results of electrostimulation are always subjective. For Toning program, with a regular program of 3-4 sessions per week, a noticeable result may be observed after 15 days. For Lipolysis and Drainage programs, 40 days of treatment are necessary. Results are obtained more quickly if treatments are combined with good physical activity and a correct life style.

#### How many sessions can I weekly perform?

For physical training, consult the technical guide that is available on the Globus website. For fitness and aesthetics programs, the number of sessions depends on the type of treatment: 3-4 sessions per week on alternate days are suggested for toning; daily treatments are permitted for Lipolysis and Drainage programs.

# **EMC** accompanying documents

## 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
	1   <b>f</b> :- +		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.
	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	Error in the data from the memory.	Execution of an incorrect program.	The machine must check the correctness of the data of the
memory.			programs. In case an error is detected, the device must restart.
Change of settings.	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 EN 60601-1-11: 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.



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