GLOBUS

ITALIAN EXCELLENCE

ELECTROSTIMULATORS

User Manual

AMI-LIFE

CE
0476

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

Dimensions: 160x99x35.4 mm
Weight: 404 g
Case: ABS
Protection level of the case: IP 20 + IP02

Use Conditions

Temperature: From 0°C to 35°C
Maximum relative humidity: 15% to 93%
Atmospheric pressure: from 700 hPa to 1060 hPa

Storage and transport conditions

Temperature: From -10°C to 45°C
Max. relative humidity: 30% - 75%
The values indicate the limits allowed if the product or the accessories are not in their original package.

Technical features of EMS currents:

Available outputs: channels 1-4
Constant current: Yes
Intensity: 0-20 mA
Waveform: rectangular, biphasic, symmetrical, compensated
Work frequency: 1-80 Hz
Pulse width: 80-260 µs

Battery charger

Brand: FLO
Model: DKT-088-0200-EU
Input: 100-240V~ 50-60Hz 0.07A
Output: 8.8V⎓ 0.2A
Polarity: 

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

The class risk of the device is IIa.

Intended use

The use of this waveform is indicated on the front of the neck and on the face. This waveform is used for the prevention of atrophy and for the rehabilitation of the swallowing muscles in the treatment of dysphagia (difficulty swallowing) of any etiology, except mechanical causes that may require surgery (for example, obstructive tumors).
Some causes of dysphagia in which it is possible to intervene include: neurological and muscular diseases, major cardiovascular and cerebrovascular events, respiratory diseases with complications for swallowing, iatrogenic diseases, fibrosis/stenosis from radiation, disuse due to stroke, intubation or anoxic birth-related injuries, head or neck trauma.

The intended use of the device is the re-education of the swallowing muscles by applying electrostimulation with biphasic, symmetrical and square waveform by means of electrodes on the surface.

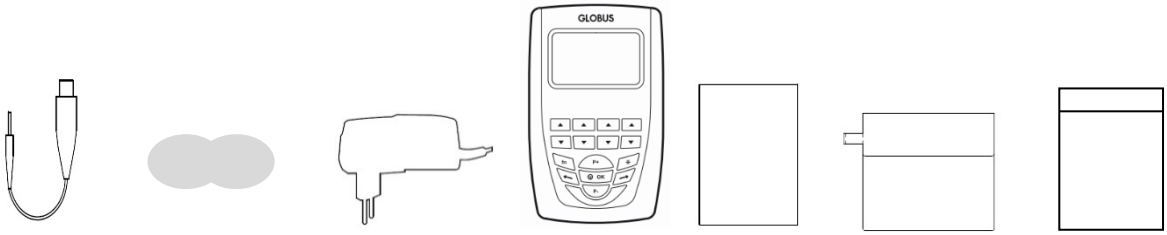
The electrostimulators are designed to be used in the following operating environments:

- clinics and medical offices;
- hospitals and long-term care facilities;
- at home only upon a doctor's prescription and after following a specific qualification course for the use of the device.

The use of this device is only intended for authorized doctors and health professionals or for the home user upon their medical prescription and supervision.

The user of these devices must have full mental capacity and be at least 18 years old.

EQUIPMENT



A B C D E F G

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.

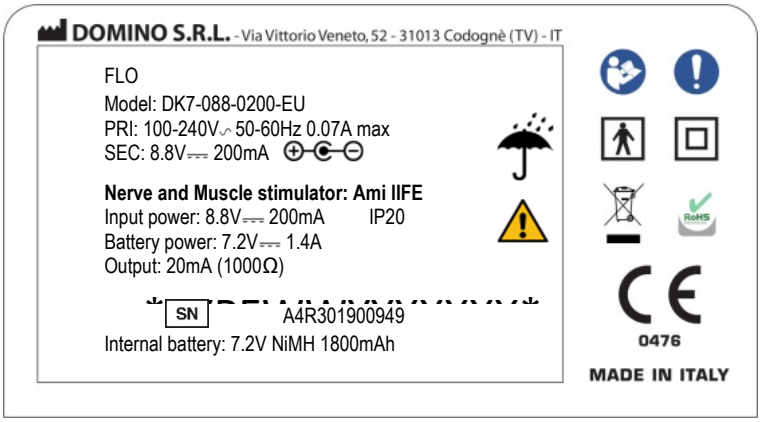
A: 4 colored cables for electrode connection
B: 2 electrodes
C: Battery charger (see technical features)
D: Device
E: User Manual
F: Carrying bag
G: Waterproof case

LABELLING AND SYMBOLS

	Warning The device can emit an output over 10mA or 10V
	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.
	Keep the device dry
	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 the product 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.
	It indicates that the product has been produced in compliance with the directive 2011/65/EEC.
	It indicates the recommended temperature for the storage and transportation of the product.
	It informs the operator that it is compulsory to read the manual before using the device.
IP 20	It indicates the water protection degree
	It indicates a compulsory behavior.

	It indicates the pressure of the environment in which the device and the accessories are transported and stored.
	It indicates the humidity of the environment where the device and the accessories are used and stored.
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
	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.
	It refers to the production lot.
	It refers to the manufacturing date.
RH	It refers to the percentage of storage humidity

Device

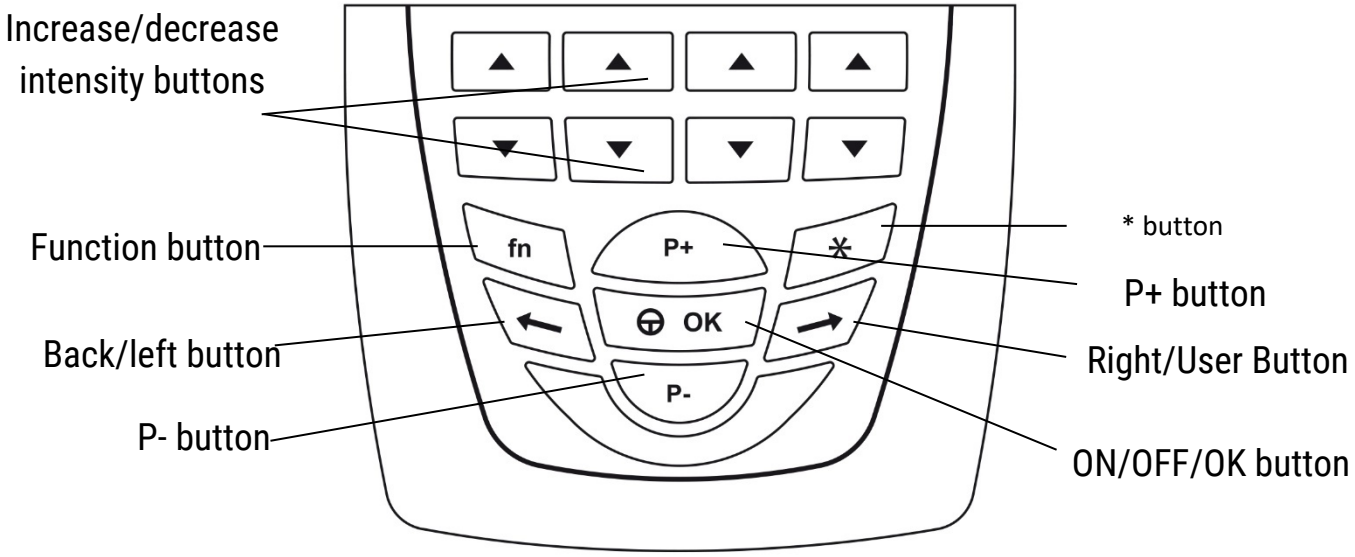


SN The first 4 digits of the serial number indicate the week and year of manufacture of the device you purchased (for example, if the code is *** 2319 *****, it means that the device was manufactured in week 23 of 2019).

Electrodes

	Refers to the type of current that can be used with the electrodes
CN15/30454	It refers to the product certification and indicates that it complies with directive 2001/95/CE updated as 2014/357/UE
	Warning
	It informs the operator that it is compulsory to read the manual before using the device.
	Indicates that the device must be disposed of correctly and not in the environment

Dashboard and keyboard

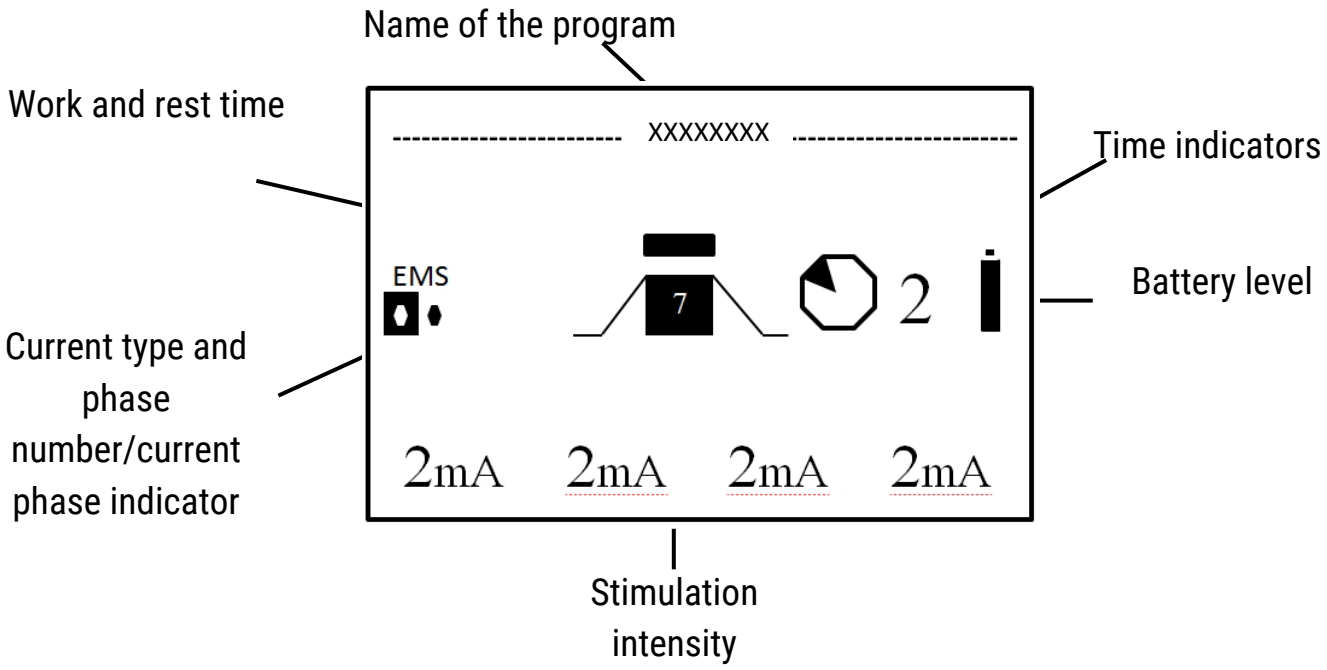


NOTE: when the 3" message appears, it means that by holding the button down for 3 seconds the function is activated.

ON/OFF/OK button	Confirm the selection. While a program is running, it activates the pause. *3"* = turning on/off.
LEFT/BACK Button	It moves the selection to the left. To go back to the previous selection. *3"* = return to the previous phase, while a 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 decreases 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 on to the next phase, while a program is running.
*** Button**	It starts and stops the contraction while "Action Now" programs are running (in the devices that include this option).

Fn (Runtime) button	If pressed in combination with other buttons, it modifies their function. If pressed alone during stimulation, it selects the Runtime mode (time, frequency and amplitude modification)
Intensity button	It increases/decreases the stimulation intensity of the corresponding channel.

Display and interface



INFORMATION SIGNS

Compliance

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

"Electrode error" information meaning

If one or more cables are not duly connected to the outputs of the device or if e.g. microcurrent cables are used to run an EMS program, the following alarm will appear on the display: "Electrode error".

PREPARING THE DEVICE FOR USE

To ensure maximum safety, the device must be used respecting the rules and the limitations indicated by 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 starting this operation, 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 from the mains.

Warnings before the use

The device works, for the stimulation part, only with batteries. The navigation of the menu, on the other hand, remains available also during charging.
Do not use the device with other electronic devices simultaneously, especially if they maintain vital functions. If the device is used nearby or on other devices, make sure it works properly. See the chapter "EMC accompanying documents".
- It is recommended to read carefully the entire operating manual before using the unit; keep this operating manual with care.
- 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 be used only by people over 18 and, in any event, who are able to understand and take action.
- It should not be used for purposes other than transcutaneous neurostimulation.
- Must be used following the indications and under the strict control of a certified physician or speech therapist;

- It must be used with transcutaneous neurostimulation electrodes suitable for the use on the front of the neck. Only use electrodes supplied by Medical Kira Srl or Globus (Domino srl).
- It 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)
- If there is any health problem, it must be used only after consulting a physician.
- The simultaneous connection of a patient to a high frequency electrosurgical device can cause burns near the electrodes of the stimulator and damage the device.
- As you turn the device on, make sure that the software version and the model of the device appear on the screen, which 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 turning-on indicates a low battery level. Recharge it as reported in the section HOW TO CHARGE THE BATTERIES.

How to connect the cables

To connect the cables to the device, plug the connectors to the intended inlets in the upper part of the unit (see picture). Plug the cables in with the grooves downward. The inlets are placed exactly under the corresponding channels.

NOTE: use any of the 4 channels with colored cables.

How to use the electrodes

Application instructions:

1. Do not apply on damaged skin
2. Clean the skin with a cleansing wipe
3. Let it dry for 30 seconds
4. Remove the electrodes from the package
5. Attach the specific cables to the electrodes
6. Remove the protective stickers placed on the side flaps
7. Peel off the electrodes from the protective film
8. Make sure you do not tamper with the gel
9. Apply the electrodes to the area to be treated
10. Secure the cables so that they do not compromise the adherence of the electrodes
11. Make sure the electrodes adhere perfectly
12. If necessary, press them gently against the skin
13. Turn on the electrostimulator and check the functionality of the electrodes

Removal instructions:

1. Turn the electrostimulator off
2. Detach the electrodes from the skin using the side adhesive flaps
3. DO NOT remove the electrodes by pulling on the cables
4. Detach the specific cables from the electrodes
5. Check the skin and apply a little emollient cream if necessary
6. Properly dispose of the electrode and protective film
7. Put the electrostimulator back in its protective case

Be careful not to roll up, pull or stretch the special cables

After use, if you want to reuse the electrode:

1. Check that the conductive gel is clean and its surface intact
2. Apply a drop of water to each conductive button and remove any remaining materials with a soft gauze
3. The gauze MUST NOT release impurities on the electrodes
4. Replace the electrodes on their protective film
5. Reinsert them in the bag and store them in a dark environment at room temperature until the next use
6. The reuse of the electrodes is only permitted on the same patient
7. The electrodes must NOT be reused if the conductive gel is damaged or not functional

8. Before starting the treatment, always check the functionality of the electrodes

Battery

The device is supplied with a set of rechargeable nickel-metal hydrate batteries (7.2V, 1.8Ah) with high performance and without memory effect.
The battery has an estimated usable life of 6 months without use. The number of re-uses (discharge and recharge) depends on the type of stimulation and the frequency with which the treatments are performed. The device is equipped with a charge indicator; it is advisable to recharge the batteries when the indicator on the display indicates ¼. If, after recharging, the number of treatments that can be performed is reduced, the battery must be replaced.

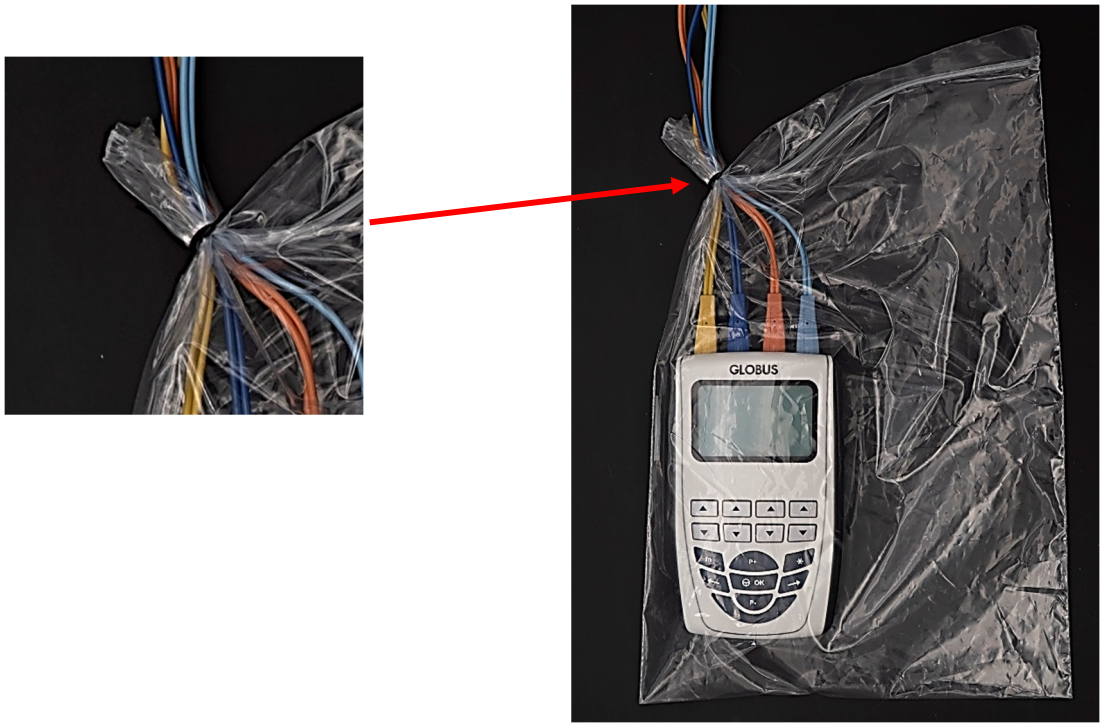
How to charge the batteries

After turning the electrostimulator off and removing the electrodes, plug it to the included power supply by putting the connector into the specific socket (see picture above). Never use a charger that is different from the one supplied with the device. Contact the customer service to replace the battery pack.

Use of the waterproof case

For home use, the device must be inserted into the IP02 waterproof case included in the package. 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 electrostimulator, please respect a few instructions.

- If the cables are damaged, replace them with original spare parts and do not use them anymore.
- Use only Medical Kira Srl or Globus (Domino srl) branded electrodes.
- Current densities higher than 2mA/cmq (effective value) for each electrode

must require special attention from the user.

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 power supply must not be wound up around the neck of people to avoid all risk of strangulation or 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 can affect the operation of the electromedical device. See the chapter "EMC accompanying documents". - Mobile and fixed radio communication devices can affect the operation of the electromedical device. See annex the chapter "EMC accompanying documents".

Contraindications

Stimulation should not be applied:

- if skin lesions or cancerous lesions are present in the treatment area
- in cases where swallowing is prevented by other concomitant neurological disorders or by structural alterations of the apparatus
- if the area to be treated has active infectious spots
- over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex
- it is absolutely forbidden to use the electrostimulator in the eye area
- if there are metal synthesis and infra-tissue metals near the areas to be treated
- on patients using pacemakers and other active implantable medical devices
- presence of severe cognitive deficits that would not allow the patient to communicate or perceive states of pain or discomfort

Relative contraindications

It is forbidden to place the device in contiguity or proximity stimulators (PM) or implantable defibrillators (ICD) or any other implantable electronic device with neuro-cardio-pulmonary action; it is also forbidden to place the electrodes in contiguity or proximity to stimulators (PM) or implantable defibrillators (ICD) or any other implantable electronic device with neuro-cardio-pulmonary action; direct stimulation with the electrodes of stimulators (PM) or implantable defibrillators (ICD) or any other implantable device with neuro-cardio-pulmonary action is expressly forbidden.

Side effects

Isolated cases of skin irritation may occur in subjects with high
skin sensitivity.
In case of allergic reaction to electrode gel, suspend the treatment and contact a specialist.
If during the treatment signs of tachycardia or extrasystole appear, suspend the electrostimulation and hear the physician.

INSTRUCTIONS FOR THE USE OF THE DEVICE

For a correct operation of the device, proceed as follows:
- connect the cables to the sockets provided in the device;
- connect the electrodes to the specific connectors at the ends of the cables;
- apply the electrodes to clean and dry skin.

Turn on

To turn on, hold the On/Off (Ok) button down for about three seconds until a sound signal is heard.
The model name and software version number will appear on the lower right-hand corner of the display.
Depending on the model purchased, the main menu items will be displayed. Use the P+ and P- buttons of the joypad to choose your function in the main menu:

“Last 10” Menu

The device stores the last ten programs executed. This way, these are available for a quick and very easy execution.
The programs are automatically stored at the end of the execution. If the memory is full, the "oldest" program is automatically deleted.
When the device turns on, select "Last 10" and then confirm with OK
With P+ and P-, 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. electrodes (positioning the electrodes)

c - delete from list

"Program List" menu

By selecting "Program List", the following areas are displayed:
- Dysphagia
- Face

Use the P+ and P- buttons of the joypad to select the desired area and press OK to confirm. The programs contained in each area will be explained at the end of the manual.

Start program

After selecting the program, the following items are displayed:
- Start
- Electrode positioning;
- Add to favorites;
- Add to treatments;
- Continue with 2+2.

To start the program, confirm with OK and increase the intensity of the channels in the next screenpage.

How to Increase and decrease intensity.

To increase/decrease the intensity of the single channels, press the increase-decrease buttons of the corresponding channels.

Display during execution

During the treatment, the screen displays the name of the program (at the top), the remaining time of the phase in progress and the type of wave used (EMS). When performing an intermittent treatment, the screen displays the work or rest phase with time countdown.

How to pause the program

To pause, press OK. 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

To stop the program in advance, turn the device off by holding OK down for about 3 seconds.

“Favorites” Menu

The "Favorites" menu allows you to save your most used programs on a special memory, up to 15 for each user. To save a program, choose the program you want to save from the "Program list". Before the execution, select "Save to Favorites" and confirm with OK.
The selected programs will be easily found in the "Favorites" menu.
NOTE : In mode 2+2, it is not possible to store programs in the Favorites area.

“Treatments” Menu

The “Treatments" menu (**Stim Lock**)allows the user to lock the device and ensure that only treatments that have been saved through the appropriate function "Save to..." on the screen before the execution of the program will be performed.

This feature has been conceived for the rental of the device to inexperienced users and/or patients who only have to perform specific protocols decided by the professional.

Activation of the Stim Lock function

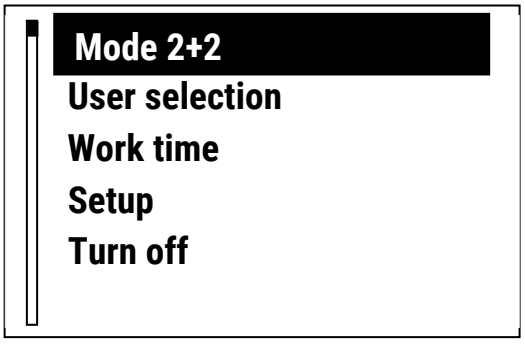
Hold the fn + → (Right) buttons down for at least 3 seconds and in any case until the area where the treatments have been saved appears.
After Stim Lock has been activated, the device will have a limited number of functions.

Deactivation of the Stim Lock function

Hold the fn + ← (Left) buttons down for at least 3 seconds 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 service.

"Advanced" menu

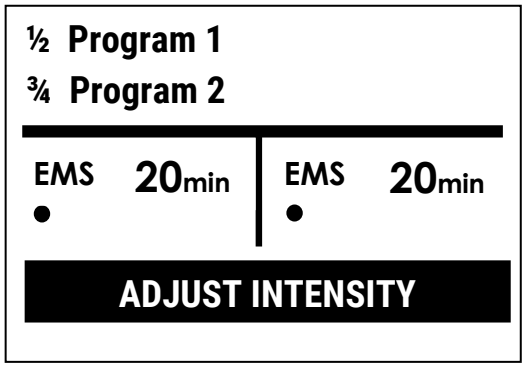
The advanced menu includes:



Mode 2+2

The device allows to execute 2 different programs at the same time, to treat two patients or two muscular groups simultaneously. How to set multiple treatments:
There are two options to run two programs simultaneously:
a) Select "2+2 mode" from the Advanced menu *
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. At this point, it is possible to select the area and the name of the second program.
** From the "Program list" menu, select the area and the desired program. At this point, select "Continue in 2 + 2" and choose the second program.

Note: during the execution in 2+2 mode, the following screen appears:



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

User selection

Allows to use the special menus (“Last 10”, “Favorites”) in a personalized way.

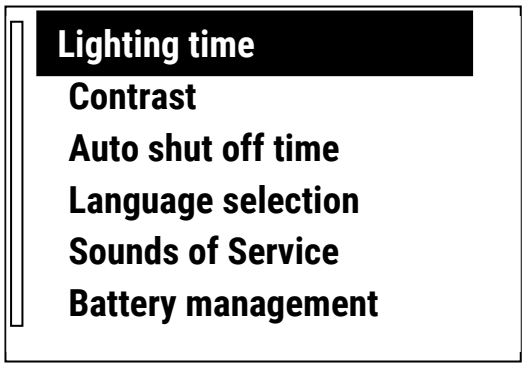
In order to have access to the favorite programs and the "Last 10", the user just has to select his/her USER. The programs stored in this area can be used only by a specific user.
NOTE : Every time the device is turned on, the latest user is displayed.

Work time

It indicates the total time the device has been used in terms of stimulation.

Setup

Selecting Setup, the following screen will appear:



- **"Lighting time" function**

Allows to vary the duration of the backlight in stand-by using the P + and P- keys.

- **"Contrast" function**

Allows to vary the contrast level of the display with P+ and P-.

- **"Auto shut off time" function**

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

- **"Language selection" function**

Allows to choose among different navigation languages by using the P+ and P- keys. Confirm the selection by pressing OK.

- **"Service sounds" function**

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

- **"Battery Management" Function**

PROGRAM LIST

The following programs have been subject to certification.

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.

Programs – Dysphagia

The list includes 3 programs with fixed, non editable parameters.

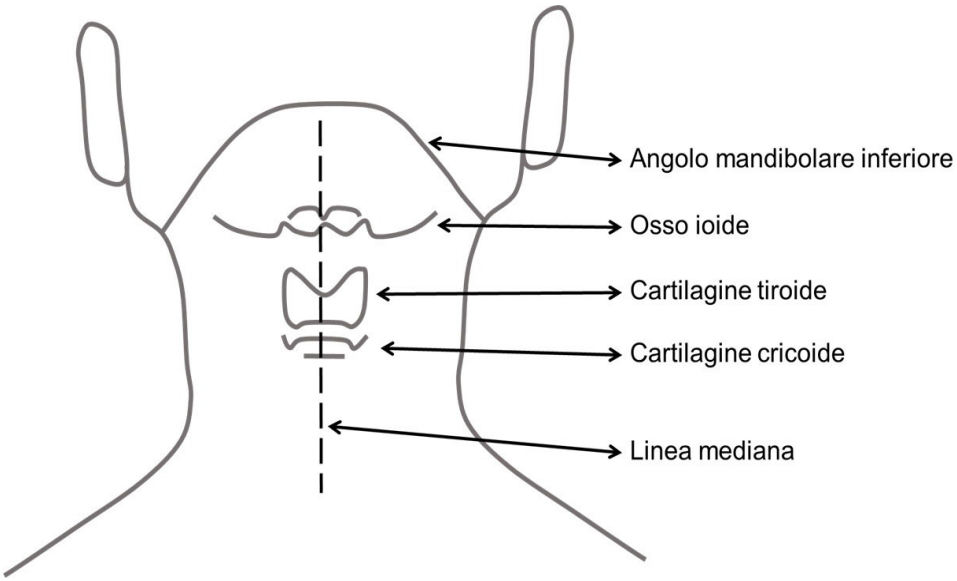
Program	Parameters
Sensory	120 µS, 80 Hz
Sensorimotor	200 µS, 80 Hz
Motor	260 µS, 80 Hz

Programs – Face

Program	Parameters	Duty cycle
Standard	200 µS, 80 Hz FIXED	NO

ELECTRODE POSITION

The main cutaneous landmarks for the position of the electrodes: lower edge of the jaw, hyoid bone, thyroid and cricoid cartilage. The midline is very important.



The figure shows the main landmarks drawn on the skin to know how to place the electrodes correctly. In all positions, the fundamental axiom is to respect the symmetry of positioning either between right and left or along the midline.

Position A

Electrodes parallel to the hyoid bone (horizontal), one in the suprahyoid and the other in the subhyoid position.

Figure 1: position A

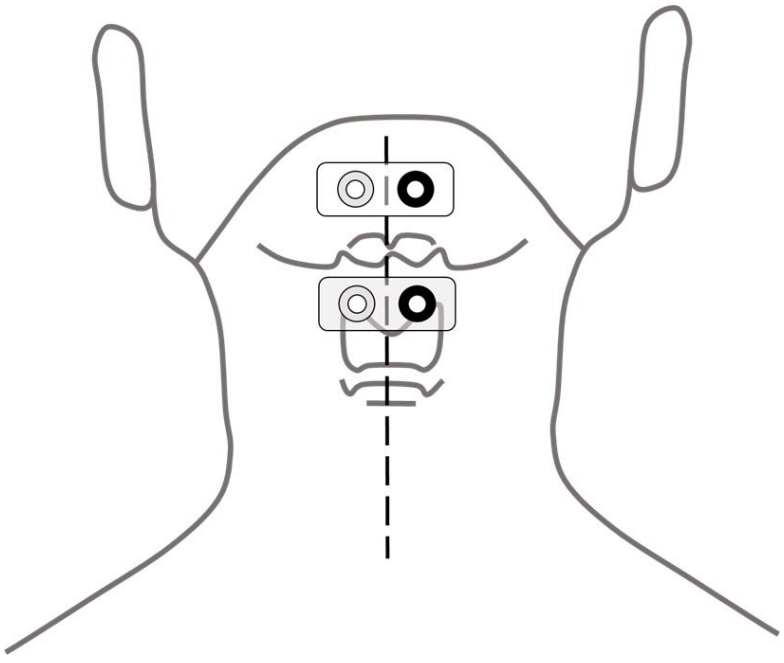


Fig.1

Variant of position A designed to optimize hypoglossal nerve recruitment.
Figure 2: position A2

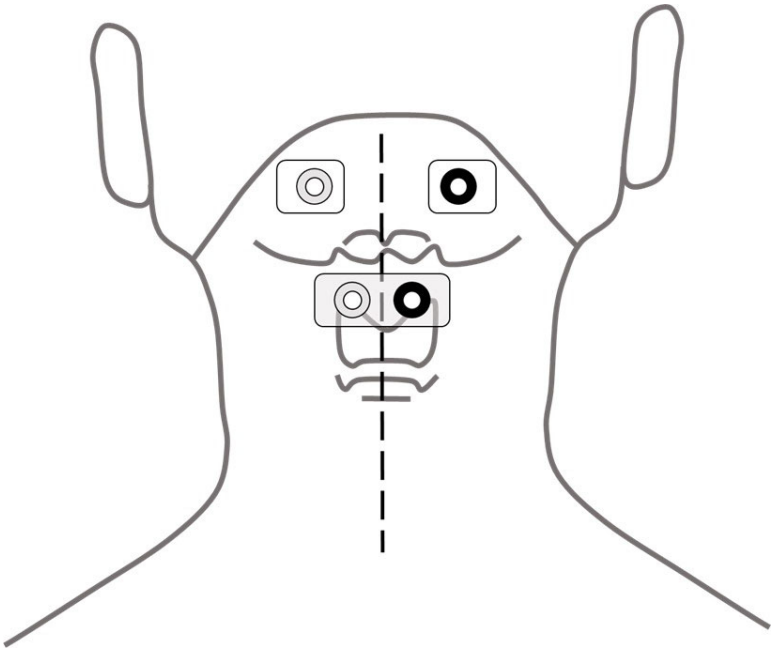


Fig.2

Position B

Electrodes subhyoid, parallel and lateral to the midline (vertical).
Figure 3: position B

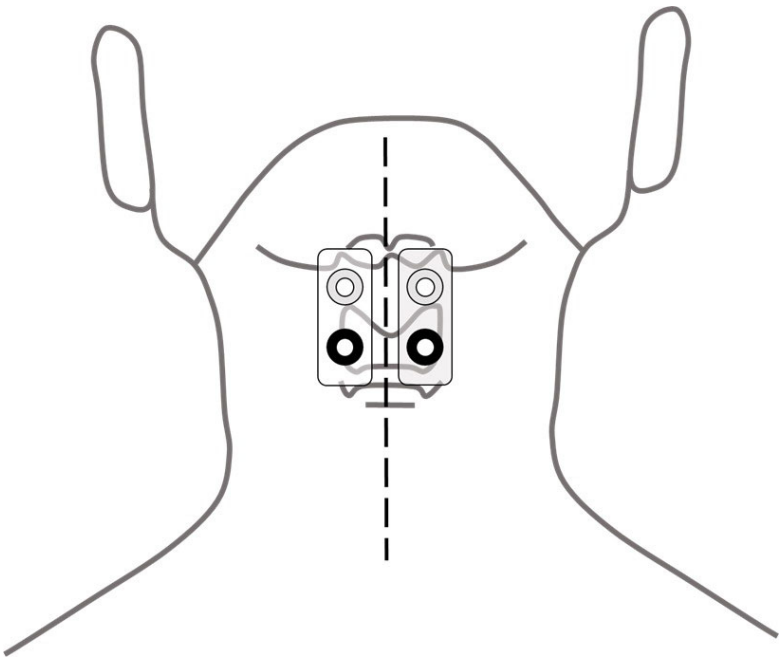


Fig.3

Variant of position B designed to optimize recruitment in very short necks or in the presence of tracheotomies.
Figure 4: position B2

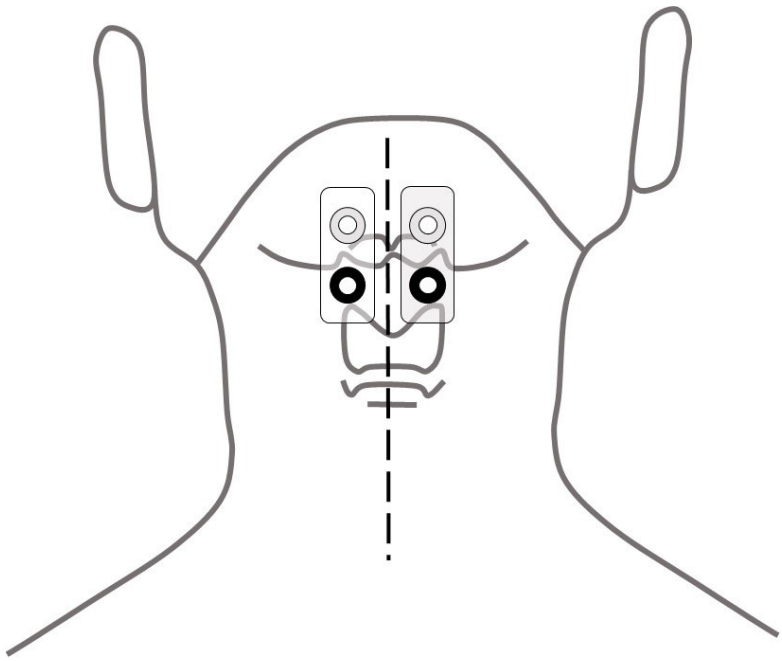


Fig.4

Variant of position B2 designed to optimize and synchronize the recruitment of tongue and suprahyoid/subhyoid muscles
Figure 5: position B3

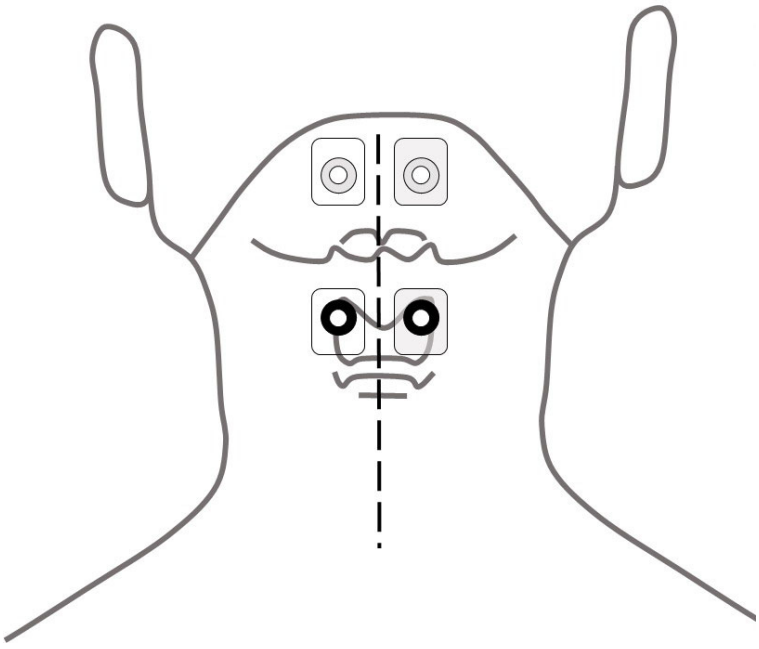


Fig.5

Position C

The copy of the suprahyoid electrodes is horizontal while the subhyoid one is vertical and median.

Figure 6: position C

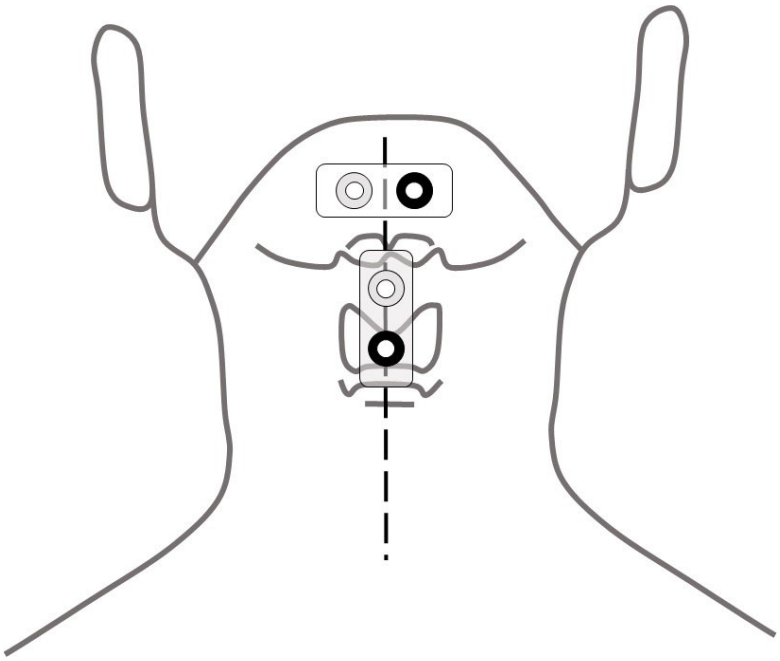


Fig.6

Variant of position C, the suprahyoid electrode is divided.

Figure 7: position C2

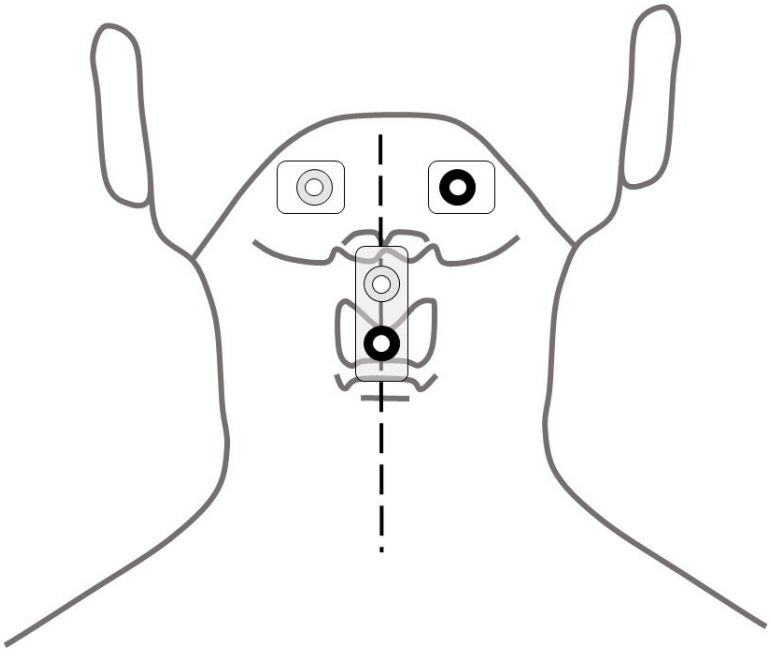


Fig.7

Variant of position C2, also called "cross".
Figure 8: position C3

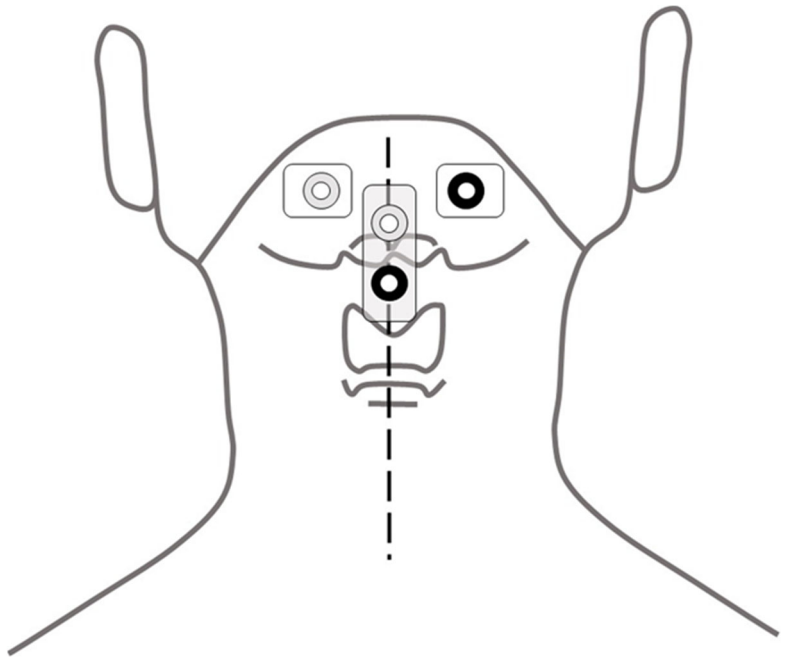


Fig.8

Position D

The copy of the suprahyoid electrodes is vertical and median while the subhyoid one is horizontal across the thyroid cartilage.
Figure 9: position D

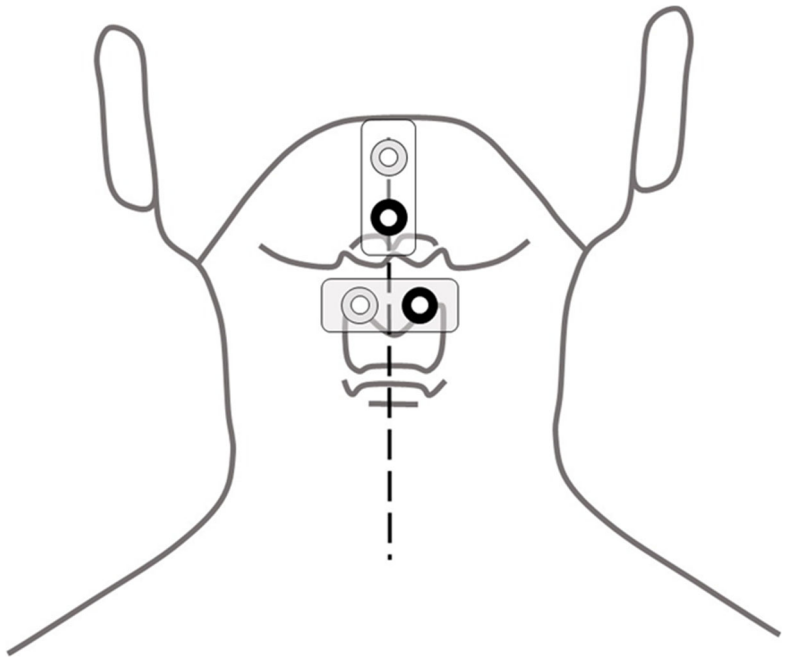


Fig.9

Position E

The two pairs of electrodes are located vertically on the midline of the neck, one suprahyoid and the other subhyoid.
Figure 10: position E

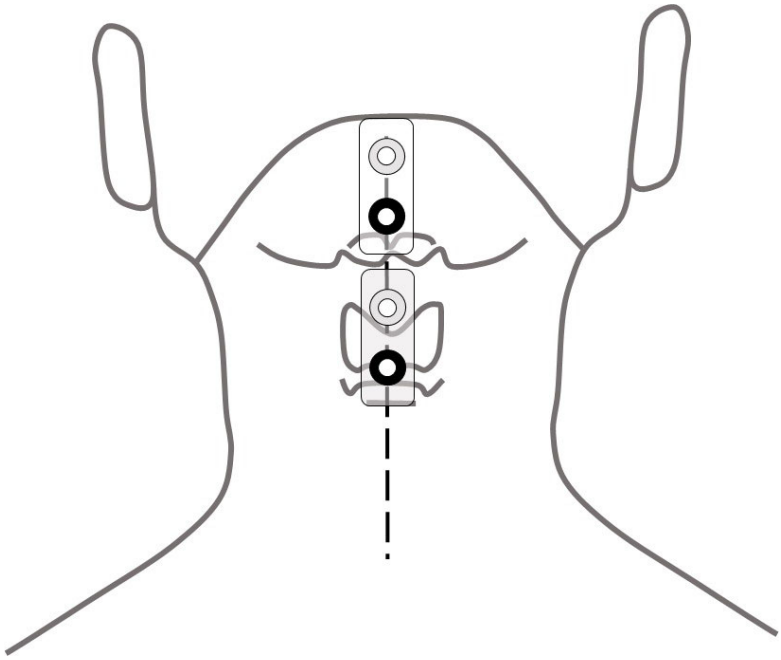


Fig.10

Position F

The two pairs of electrodes are both in a suprahyoid position and parallel to the lower edge of the mandible, position known as the "anterior digastric".
Figure 11: position F

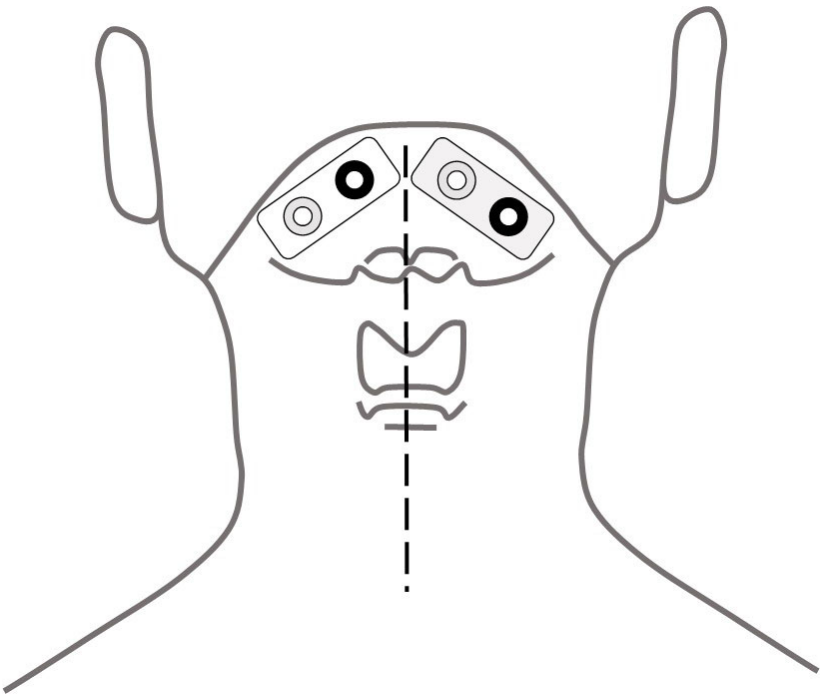


Fig.11

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 the electrostimulator in a dry and open environment. (Do not wrap it with other objects.)
- Clean the electrostimulator only with disinfectant with sodium hypochlorite or quaternary ammonium salt (percentage: 0.2-0.3%) diluted with distilled water. After cleaning/disinfecting the device, it must be dried perfectly with a clean cloth.
- The parts should be cleaned/disinfected 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 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

If the cables or the electrodes are damaged, these should be replaced and not used anymore.

Before placing the electrodes on the skin, we suggest cleaning it accurately. After using single-patient and/or single-use multipurpose electrodes these should be stored using their own plastic film and placed in a clean and closed plastic bag.

Make sure that the electrodes do not touch each other and do not overlie one over the other.
Once the package has been opened, the electrodes can be used for 25-30 applications. The electrodes must always be replaced if they do not stay perfectly in contact with the skin.
If non self-adhesive electrodes are used, it is advisable to clean their surface with specific cleansers that respect the requirements described in the manual.
Handle 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 software supports such as 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 any 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. The products have to be sent for repairs by and at the expenses of the Customer in their original packages and with their 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 impossibility 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 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.

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 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 machine must continue the treatment, signaling that operation is carried out in battery mode.
	Detachment of an electrode.	Unpleasant stimulation or painful electric shock in case of reconnection of the electrode.	The machine must monitor the current constantly on each channel set beyond 9mA. In case the detected current is below a certain threshold, the machine must rest the current of the channel.
	Failure to detect microcurrent cable.	Dangerous stimulation.	The machine must report an error relating to the electrodes and prevent the program from starting.
	Too intense current setting in the case of microcurrents.	Dangerous stimulation.	The machine must downgrade the voltage boost stage to prevent the supply of current beyond the maximum value.
			The machine must not start the microcurrent treatment if it does not detect the hardware downgrading of the voltage boost converter 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. If an error is detected, the device must remove the program from the program list.
Loading machine settings.	Setting data memory error.	Impaired operation.	The machine must check the correctness of the setting data and, in the event of errors, it must

			load the default settings present in copy in the memory and indicate on the display that the reset has been carried out.
		Unreadable display.	The machine must check the value of the contrast setting. If it is out of range, the machine 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 Ami Life. Otherwise the performance of Ami Life may be affected.

GLOBUS

ITALIAN EXCELLENCE

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