















DEAR CUSTOMER

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

| ELIT | |
|------|--|
|------|--|

The electrostimulators A1R (Elite) are manufactured by:

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This product has been manufactured according to the technical regulations in force and is certified according to Directive 93/42/EEC updated by 2007/47 directive for medical devices, by Notified Body n. 0197.





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TECHNICAL FEATURES

Device

Size: 160x99x35.4 mm

Weight: 404 g

Case: in Food Grade ABS

Protection level: IP 22

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

Max. relative humidity: 30% - 75%

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

Conditions of use

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: 0-100 mA with 1000 Ohm load

Wave form: Rectangular, biphasic, symmetrical,

compensated

Working frequency:

Recovery frequency:

Pulse amplitude:

0.3-150 Hz

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 µseconds

Charger

Brand: FLO

model: DKT-088-0200-EU

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

Output: 8,8 Vd.c. 0.2A

Polarity:

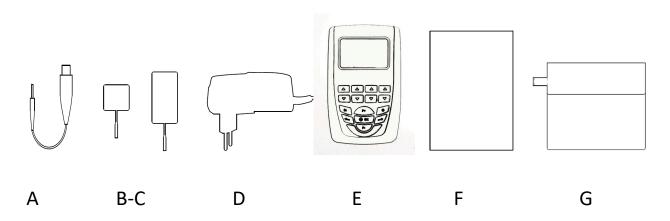


ELITE

Battery

Battery pack: Ni-MH 7,2 V 1,8 Ah

EQUIPMENT



The electrostimulator is supplied complete of cables and electrodes: therefore, please check that the package contains the complete equipment. If some elements are not contained in the package, please contact immediately the authorized retailer where you purchased the product.

Control the integrity of the device and its electrodes carefully.

- A. 4 colored electrode connection cables (for EMS and TENS treatments)
- B. A bag containing 4 reusable self-adhesive electrodes (50 x 50 mm) (for small areas such as upper limbs, calves, cervical area...)
- C. A bag containing 4 reusable self-adhesive electrodes (50 x 90 mm) (for large areas such as thighs, abdomen and gluteal muscles...)
- D. Charger (See technical features)
- E. A1R Unit
- F. User manual Warranty
- G. Carrying bag

All the supplied information can be modified without prior notice.

The device can be used with some optional accessories (for further info, visit the website www.globuscorporation.com).

If you are interested in buying these accessories, please contact the retailer.

Accessories not included (available on charge)

- Motor point pen
- Kit of 8 elastic bands for legs and thighs





- Kit of 4 elastic bands for thighs
- Face electrodes
- Kit Y cables

INTENDED USE

The service life of the product is estimated at 5 years. It is advisable to return the product for maintenance and security checks every two years. The number of treatments depends on the battery charge. The duration of the battery is 6 months; thereafter its replacement is recommended.

The electrostimulators are intended for use in the following operating environments:

- domestic environment;
- clinics:
- physiotherapy centers;
- rehabilitation centers;
- general pain treatments;
- beauty and sport purposes;

The device can be used by patients (appropriately informed about the conditions of use) and the medical staff only.



ELITE



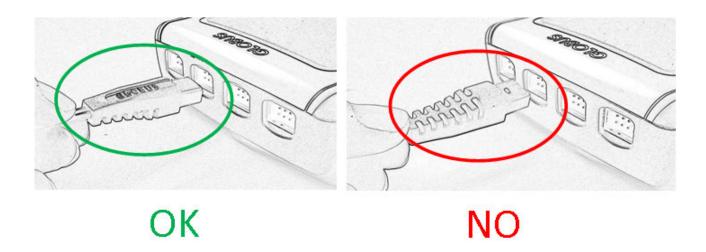
CONNECTIONS

Cable connection outlets and power supply

Attention:

If the package, the cable or the connector of the charger show signs of wear or damage, replace them instantly.

How to connect the cables



Plug the connectors in the slots in the upper part of the unit to connect the diffusers to the device (see pic.). When plugging in the cable, the grooves of the cable have to be oriented downwards. The inlets are placed exactly under the corresponding channels.

ATTENTION: the images are for illustrative purposes only to show the correct insertion of the connectors into the appropriate slots. It is recommended to unplug the connectors grabbing the final part with the grooves and not pulling them taking the cable in the middle.

NOTE: For EMS and TENS currents, the 4 channels with colored cables can be used indifferently.

Electrode application

Remove the electrodes from the original package; all new electrodes have a seal on the package. Ensure that the device is off. First, connect the two cable plugs to the electrodes, then disconnect the electrodes from their position and apply them on the skin. See the pictures included in this manual to place the electrodes correctly.

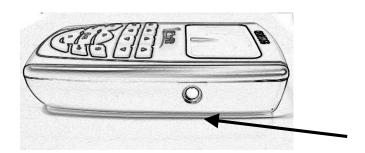
After use, place the electrodes in their original position again.





ATTENTION: Do not unplug the electrodes if the unit is working.

Battery: how to charge the batteries



The device is supplied with a set of rechargeable nickel-metal hydrate batteries (7.2V, 1.5Ah).

Recharge the batteries when the battery indicator on the display indicates 1/4.

To charge the batteries, turn off the electrostimulator and disconnect the electrodes, then connect the electrostimulator to the charger provided by plugging it in the appropriate inlet (see picture above).

Use the charger contained in the package only. Contact the authorized service center to replace the batteries.





LABELLING AND SYMBOLS



| | It refers to the manufacturer |
|-----------------|---|
| | Warning |
| (€ 0197 | This symbol on your device indicates that it complies with the directives on medical devices (93/42/EEC 47/2007/EEC. |
| | It indicates that this is a II class device. |
| † | It indicates that this device has type BF parts. |
| | WEEE symbol (Waste of Electrical and Electronic Equipment). Recycling symbol. The WEEE symbol used for this product indicates that the device may not be disposed of as a household product. Properly dispose of the product to help protect the environment. For more information on recycling this product, contact the local competent department, the household waste management company or the store in which the product was purchased. |
| ROHS | It indicates that the product has been produced respecting the directive 2011/65/EEC. |
| <i></i> | It indicates the optimal temperatures for the storage and transportation of the product. |
| | It informs the operator that before using the device he must read the manual. |
| IP22 | It indicates the water protection degree |
| 0 | It informs the operator of a compulsory conduct |
| □ | It refers to the pressure of the storage and transport environment where the device and its accessories are used |





| <u></u> | It refers to the humidity of the storage and transport environment where the device and its accessories are used. |
|--------------|---|
| Output Power | It indicates the output power of the device |
| Input | Input: it indicates the value of the mains voltage for the power supply unit |
| Output | Output: - it indicates the power supply unit outbound voltage - it indicates the maximum power value of the magnetic field emitted by the device - it indicates the range of frequencies of the magnetic field emitted by the device" |
| Туре | It indicates the device type |
| Power | It indicates the power supply unit model of the device |
| Battery | It indicates the battery pack inside the device |
| | It refers to the expiry date |
| LOT | It refers to the production lot |
| | It refers to the manufacturing date |
| PE | Polythene symbol |

Device

Input DK7-088-0200-EU PRI: 100-240Vac 50-60Hz 0,2A

Sec; 8,8VDC 200mA Output 120mA (1000ohm) Electrostimulator Model: ELITE

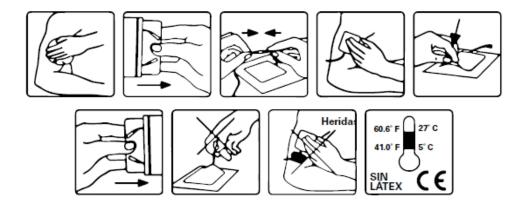
SN 41R401507285

Batteries Ni-Mh : 7,2V NiMh ≥1500mAh





Electrodes



The supplied electrodes can be used on a single patient. They are self-adhesive, reusable and pregelled. The electrode cable is female. The electrodes are labeled "CE" in compliance with Directive 93/42/EEC for medical devices. All the supplied information can be modified without prior notice.

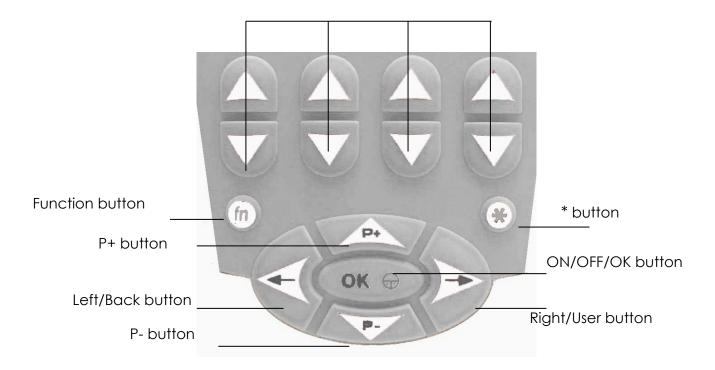




PANEL AND KEYBOARD

Keyboard

Increase/Decrease intensity button



NOTE: When the 3" message appears, it means that pressing the button for 3 seconds the function is activated.

ON/OFF/OK Button It confirms the selection. While a program is running, it

activates the pause.

3" = ON/OFF.

Left/BACK Button It moves the selection to the left.

It returns to the previous selection.

3" = While a program is running, it returns to the previous

phase.

P+ Button It moves the selection upwards.

While a program is running, it increases the intensity of the

4 channels simultaneously.

P- Button It moves the selection downwards.

While a program is running, it decreases the intensity of

the 4 channels simultaneously.

Right/USER Button It moves the selection to the right.

3" = While a program is running, it moves to the next

phase.





* **Button** Service button disabled.

fn button If pressed together with other buttons, it modifies their

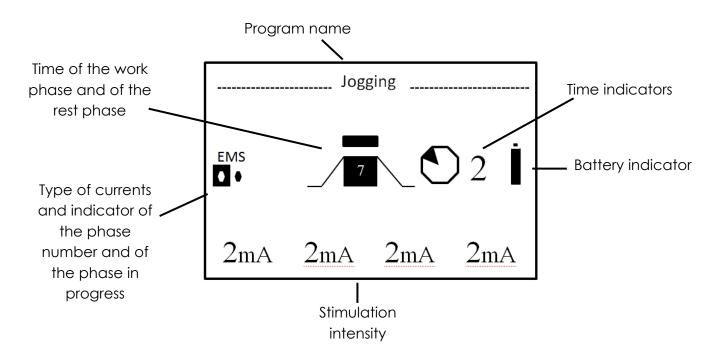
function; if pressed singularly during the stimulation, it permits the access to the Runtime function (to modify time,

frequency and amplitude).

Intensity button It increases/decreases the stimulation intensity of the

corresponding channel.

Display and interface



ALARMS

Compliance

Certifications: CE MDD certificate.

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

Meaning of the "Electrode error" alarm

If one or more cables are not connected to the mains, the message "Electrode error" will appear on the display.



WARNINGS AND CONTRAINDICATIONS



Mandatory behavior

For safety reasons, the device must be used exclusively as indicated in the present manual.

Do not perform the treatment in case of skin lesions.

If the package, the cable or the charger connector show signs of wear or damage, replace them instantly.

The unit has to be connected to the mains by its power supply unit. Before starting the treatment, ensure that the building wires comply with the directives in force in your country. Ensure that the power supply unit is in a comfortable position and can be easily unplugged.

The producer declines all responsibility related to any misuse or mishandling of the device.

Electronic or manual reproduction of part or all of the contents of the present manual is strictly forbidden without producer's prior permission.

Warnings before use

Do not use Elite combined with other electronic devices, especially if they maintain vital functions. Read the tables at the end of the present manual for a correct use of Elite. If the device is used nearby or on other electromedical equipment, ensure that Elite works properly.

- Read the present manual carefully before using the device. Keep the present manual in a safe place;
- The current emitted by the device is higher than 10mArms.
- Checking the integrity of the device before each use is a fundamental requirement to perform the therapy correctly. The device must not be used if the buttons or cables are defective or malfunctioning.

The device:

- has to be used for neuromuscular stimulation only and as described in this manual;
- has to be used for transcutaneous neuromuscular stimulation only.
- has to be used according to the indications in the present manual and under the physician's or physiotherapist's supervision;
- has to be used with the electrodes included in the package and specifically intended for transcutaneous neuromuscular stimulation;
- has to be kept out of the reach of children;
- ECG monitoring devices may not operate properly when electrostimulation is working.
- has not to be used in transthoracic modality because it may cause cardiac arrhythmia, interfering with the heart frequency. Do not stimulate the pectoral and dorsal muscles simultaneously;
- in case of health problems, consult the doctor before use;



- the simultaneous use of high-frequency electrosurgery device may sear the skin near the electrodes and damage the electrostimulator;
- Check whether the software version and the device model appear during startup, which means that the device is working correctly.

Otherwise, if all the segments do not appear on the monitor, shut down the device and restart it. If the problem persists, contact the customer care and do not use the device.

- If the device switches off unexpectedly, the battery is likely to be out of charge and has to be recharged according to the instructions in the section HOW TO CHARGE THE BATTERIES.

Warnings during use

While using the electrostimulator, please comply with the following indications:

- damaged cables have to be replaced with original, brand-new parts;
- use only Globus electrodes;
- pay particular attention when the current density for every electrode is above 2mA/cm² (effective value);
- keep the device out of the reach of any pet which could damage it and contaminate the electrodes and its accessories with parasites;
- the cables must never be wound up around the neck, since it may lead to strangulation and suffocation;
- mobile and fixed radio-communication devices may affect the functioning of Elite; read the tables in the present manual for more info.

Preventative measures for incontinence treatments.

- Do not use the device on patients with extra-urethral incontinence.
- Do not use the device on patients suffering from excessive incontinence owing to evacuation disorders.
- Do not use the device on patients with severe urinary retention to the upper urinary passages.
- Do not use the device on patients with total peripheral denervation of the pelvic floor.
- Patients suffering from a total/subtotal prolapse of the uterus/vagina have to be stimulated with extreme care.
- Patients with infections to the urinary passages should be treated for these symptoms first, before starting the stimulation treatment.
- Before removing or touching the probe, it is necessary to turn off the stimulator or to regulate the intensity of both channels to 0.0 mA.
- Since the treatment is a personalized medical prescription, do not lend the stimulator to non-authorized persons.





Side effects

Isolated cases of skin irritation may occur in patients with particularly sensitive skin. In case of an allergic reaction to the electrode gel, suspend the treatment and contact a specialist.

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

Contraindications

Do not use the device in the following cases:

- Stimulation of the front neck (carotid sinus);
- Pacemaker wearers;
- Patients with tumor diseases (see your oncologist);
- Stimulation of the brain region;
- Pains whose etiology is unknown;
- Ulcers and dermatological disorders;
- Severe traumas.
- Stimulation on recent scars.
- Pregnancy.
- It is strictly forbidden to use the electrostimulator on the ocular area.
- Near body areas with osteosynthesis implants (prostheses, coils, screws, orthopedic plates), when using monophasic current, interferential or continuous current and ionophoresis.

It is recommended to use the device carefully on people presenting with capillary fragility, as an excessive stimulation could cause capillary rupture.



MAINTENANCE AND CLEANING

Device

- In case of malfunctioning, do not open or tamper with the device nor try to repair it by yourself.
- Only specialized and authorized centers can repair the device.
- Avoid violent impacts that may damage the device and cause its malfunctioning (even if not immediately detectable).
- Use the device in a dry and open environment. Do not wrap the device.
- Clean the device and accessories only with disinfectant with sodium hypochlorite or quaternary ammonium salt diluted with distilled water (percentage 0.2-0.3%). After cleaning/disinfecting it, dry the device and its accessories with a clean cloth.
- It is recommended to clean/disinfect the parts after every use, unless otherwise indicated.
- Always use the device and its accessories with clean hands.
- It is recommended to use the device in a clean room, to avoid contamination with dust and dirt.
- It is recommended to use the device in a well-ventilated space.

Battery

Battery info

A specific menu allows the user to visualize the charge and the state of the battery. It is recommended to access the menu only if the batteries are completely charged.

From the main menu select "Setup" and then "Battery info".

Six codes will be visualized:

COD1 = 0 expected voltage threshold reached.

COD1 = 1 max. charge time reached.

COD2 = value of the battery voltage at the beginning of the charge.

COD3 = value of the battery voltage at the end of the charge.

COD4 = charge duration (from 1 to 840 minutes, ideal time 720 minutes).

COD5 = duration of the charger/power supply connection.

COD6 = voltage of the battery pack.

According to the above-mentioned values, it is advisable to replace the battery when COD1 = 1 and COD3 < 7,4 volts, or when COD3-COD2 >= 2 volts and COD4 <600, or, again, when COD6 is lower than 5,8 volts.

Furthermore, it is recommended to replace the battery pack after 3 months of inactivity. After that period, batteries generally lose their charging capacity, which may render the recharge dangerous.



Accessories

Use and storage of the electrodes and the cables.

Worn-out cables or electrodes have to be replaced with brand-new parts.

Skin has to be cleaned accurately before applying the electrodes.

After using the multi-purpose or single-use, single-patient electrodes, they have to be placed in their plastic film and stored in the plastic bag.

Avoid that the electrodes touch each other or lay one over the other.

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

The electrodes have to be always used with clean hands and replaced if they do not adhere to the skin.

If not using self-adhesive electrodes, it is advisable to clean the surface with proper cleansers that respect the requirements described in the manual.

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

After the end of a 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 the electrodes, they must be folded up and placed in the plastic bags supplied with the cables.

Disposal of the device

Do not burn the device or part of it, but dispose of the product in the specialized centers and respecting the directives in force in your country.

When the product has to be disposed, the user can return it to the retailer when purchasing a new unit.

Following the previous indications and correct separate waste collection contribute to avoiding possible negative effects on the environment and health and promote the reuse and/or recycle of materials which the device is composed of. The illegal disposal of the product entails the application of an administrative fine according to the current regulations.





INSTRUCTIONS FOR USE

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

- Connect the cables to the outlets on the unit.
- Connect the electrodes to the connectors at the end of the cables.
- Place the electrodes on the skin.

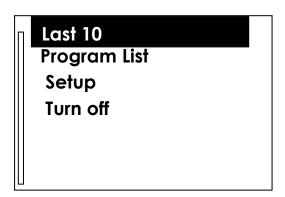
Start up

Turn on the electrostimulator by pressing the ON/OFF/OK button for 3 seconds until hearing a tone.

The names of the unit and of the software version appear on the right-bottom corner of the display.

The entries of the main menu may vary according to single models.

Use the P+ and P- buttons on the keyboard to scroll the menu:





"Program List" menu

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

- SPORT
- FITNESS-PHYSICAL SHAPE
- BEAUTY-AESTETHICS
- PAIN-ANTALGIC
- REHABILITATION

Program selection

- Area selection:

Press P+ or P- to 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 placement;

Select Start to start the program and increase the channel intensity in the following screen.

Increase/decrease intensity

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



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

Visualization during a program execution

While a treatment is executing, the display shows the name of the program (at the top), the number of total phases and the phase in progress, the remaining time of the phase in progress and the type of the wave used (EMS, TENS...). In the programs with intermittent stimulation, the time countdown graphically represents the work or the rest phase.

How to pause a program

Press OK to pause a program and eventually press OK again to return to the program. The intensity indicators will be reset to zero every time the treatment is stopped or restarted.

How to modify the duration of the treatment

When a program is running you can press the fn button to modify the duration of the treatment. After pressing the fn button increase or decrease the duration of the phase using the P + and P- buttons.

How to stop a program

When stopping a program before its end, hold down OK for 3 seconds to turn the device off.

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.





Last10

"Last 10" menu

The electrostimulator stores the latest 10 executed programs, which will be available for a rapid and easy execution.

A program is stored automatically at the end of the execution. When the memory is full, older programs are automatically deleted.

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

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

(If no program is stored, 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. When placing the cursor on "Electrode placement", a brief guide for the correct placement of the electrodes is displayed.

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

c. When 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 3, plus the default user, defined as USER 0) can have their own "Last 10" memory



"Setup" menu

The setup menu includes the following entries:

User selection
Language selection
Service sounds
Auto shut off time
Contrast
Battery info





• User Selection

It permits the use of the special menus ("Last 10") in a personalized manner. Users can store their programs in "Last 10" and perform them only when entering their specific account. The same procedure applies to the "Last ten" programs. NOTE: Every time the device has been turned on, the latest user will be displayed.

• Language selection

It permits the user to choose among 5 different languages. Press P+ and P- to select the language and press OK to confirm.

• Service sounds

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

• Auto shut off time

It permits the user to set the automatic shut-down after a certain period of inactivity. Press P+ and P- to regulate the time.

• Contrast

It permits the user to modify the contrast level in the display, by pressing P+ and P-.

• Battery info



Turn off

It turns off the device.



ACTION PRINCIPLES

Muscular electrostimulation

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

Each side of the human body approximately includes 200 muscles (about 400 muscles overall) most of which are striated or voluntary.

The physiology of muscular contraction

The skeletal muscle performs its functions through the contraction mechanism.

When a person decides to make a movement, the motor center of the brain sends an electric signal to the contracting muscle.

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 amount of energy needed for the contraction is provided by the adenosine triphosphate (ATP) and is supported by an energy recharging system based on aerobic and anaerobic energy mechanisms which use carbohydrates and fats. In other words, electric stimulation is not a direct source of energy but it works as a tool that causes a muscular contraction.

The same type of mechanism is activated when the muscular contraction is produced by the EMS; they have the same function of a pulse naturally transmitted by the motor nervous system. When the contraction is over, the muscle relaxes and returns to its original state.

Isotonic and isometric contraction

An isotonic contraction occurs when, during a movement, the interested muscles exceed the external resistance by shortening, thus provoking a constant state of tension in the ends of the tendons. When the external resistance impedes its movement, the muscular contraction, instead of provoking a shortening effect, causes an increase in the tension at the extremes; this is an isometric contraction. In the case of electrostimulation, an isometric stimulation is normally used because it permits a more powerful and efficient contraction.

The distribution of different types of fibers in the muscle

The relation between the two main categories (type I and type II) can vary noticeably.

There are muscular groups that are typically made up of type I fibers, like the soleus, and muscles which are made up of only type II fibers, like the orbicular muscle, but the majority of the human body muscles are composed of a combination of the two types. Studies on the distribution of fibers in the muscle mass have highlighted



the close relation between the motoneuron (tonic or phasic) and the functional characteristics of the fibers it innervates and, moreover, they have shown how a specific motor activity (particularly sports) can bring about a functional adaptation of fibers and a change in their metabolic characteristics.

| 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 |

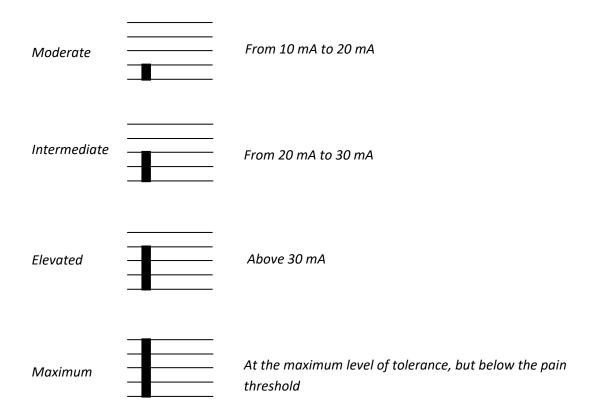
Stimulation intensity

The current intensity necessary to obtain a muscular contraction is personal and depends on the position of the electrodes, the underlying adipose tissue, sweating, the presence of hair on the treatment field, etc.. Therefore, the same current intensity may generate different feelings according to different persons, days and sides of the body. During the same working session, it will be necessary to regulate the intensity in order to obtain the same level of contraction because of the accommodation phenomenon. The current intensities recommended in the different phases are proposed as indicative values, and each person should modify these levels according to his/her personal needs.

- Moderate intensity. The muscle does not tire, not even during prolonged treatments. The contraction induced is tolerable and pleasant. This is the first level on the graphic representation of intensity.
- Intermediate intensity. The muscle is visibly contracted but the stimulation does not cause the movement of the joints. This is the second level on the graphic representation of intensity.
- Elevated intensity. The muscle is contracted substantially. The muscular contraction will cause the extension or bending of the limb if this is not blocked. This is the third level on the graphic representation of intensity.
- Maximum intensity. The muscle is contracted maximally. This is an intense treatment that should be performed only after having executed different applications at lower intensity.







The descriptions of the treatments contain the recommended intensity levels. NOTE: The recommended current levels are only indicative.

Open circuit

ELITE is equipped with a monitoring device of power emissions. If the operator increases the intensity level above 10 mA and the circuit is open (the cables are not connected to the device and the electrodes are not applied to the skin), the electrostimulator immediately sets the intensity to 0 mA. Therefore, before starting a program, ensure that the cables are connected to the device and that the electrodes are not worn-out, as their conduction capacity may be reduced.

Tens

Transcutaneous Electrical Nerve Stimulation (TENS) is a selective stimulation of the large fibers of the peripheral nerves contributing to the closing of the gate entrance for the nociceptors and increasing the release of endorphinic substances, thus reducing pain intensity. Therefore TENS has been conceived to treat the severe and chronic pain related to the main musculoskeletal disorders.

The decrease of pain following to the TENS current application is induced by these factors:

- a. Gate control theory
- b. Endorphin secretion
- c. Different sedative effects in relation with frequency



Gate theory

If the electric signals that lead information related to pain to the brain are stopped, also the pain perception is eliminated. If, for instance, we hit our head against an object, the first thing we do is to massage the area affected by the trauma. Thus, we stimulate the receptors related to touch and pressure. TENS in continuous mode and in frequency modulation can be used to generate signals similar to touch and pressure signals. If their intensity is sufficient, their priority is so high that it prevails on the pain signals. Once the priority is acquired, the gate related to the sensory signals is opened and gate related to pain 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 and called synapse. The synapse can be seen as the space between the end of a nerve and the beginning 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. This process is repeated until the signal reaches the brain. The opioids involved in the pain reduction slide in the synapse space and impede the neurotransmitter propagation, thus blocking the pain signals. The endorphins are opioids naturally produced by the body to tackle the pain and they can act both on the marrow and on the brain, in this way they are effective analgesics. Tens can increase the natural production of endorphins and, therefore, they decrease the pain perception.

Different effects in relation with the frequency

Depending on the frequency used, ELITE produces immediate short-term antalgic effects (higher frequencies) or progressive long-term effects (lower frequencies).



TOTAL 32



PROGRAM LIST

| Sport Program List |
|------------------------------------|
| Capillarization |
| Warm-up |
| Decontracting |
| Post-competition recovery/training |
| Maximum strength |
| Endurance strength |
| Explosive strength |
| Reactivity |
| Demo |
| Motor point pen |

NOTE: some programs are divided between man and woman according to body areas.

Fitness-Physical shape program List

| Firming | |
|-------------------|--|
| Bio-Pulse firming | |
| Sculpting | |
| Toning | |
| Mass Building | |
| Total 26 | |

NOTE: some programs are divided between man and woman according to body areas.





Beauthy-Aestethics Program List

| Drainage |
|----------------------------|
| Bio-Pulse drainage |
| Lipolysis |
| Bio-Pulse lipolysis |
| Toning massage |
| Bio-Pulse relaxing massage |
| Vascularization |
| Face capillarization |
| Face lifting effect |
| Total 29 |

NOTE: the programs are divided between man and woman according to body areas.





Medical currents - Pain Antalgic (Tens) Program List

The following programs are medical

| _Antalgic tens |
|------------------|
| Endorphinic tens |
| Contractures |
| _ Hematomas |
| Sciatica |
| Lumbago |
| Cervical pain |
| Shoulder pain |
| _Epicondylitis |
| Total 9 |
| |

.

Medical currents - Rehabilitation Program List

The following programs are medical

Lower limbs atrophy recovery

Upper limbs atrophy recovery

Total 2

NOTE

For further information about the programs, please visit our website, where you can download a complete guide containing all the indications to perform the treatment correctly.





GENERAL NOTES ON ELECTRODE PLACEMENT

The correct positioning of the electrodes and the correct choice of their size are fundamental to guarantee the efficiency of the treatment.

The images at the end of the present manual illustrate the different sizes of the electrodes and their positioning. For more information, please visit our website www.globuscorporation.com where you can find a wide range of images and videos on the placement of the electrodes.

NOTE In all the programs that cause an important muscle contraction (such as, for example, strength, hyperthrophy, toning and firming programs...) it is important to place the electrode on the muscle **motor point**, which is the most sensitive point to stimulation.

If the electrode is not placed exactly on the motor point, the contraction could be small and/or annoying. In this case it is necessary to move the positive electrode a few millimeters up to feel an effective and comfortable contraction.

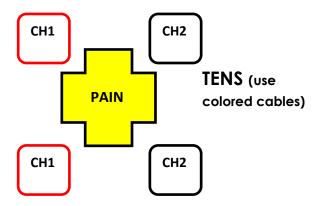
The position of the body during the stimulation

The position of the body during the electrostimulation session depends on the body part involved and on the program type. During the treatment execution with high intensities, we suggest blocking the limbs in order to work in isometry. For instance, if you want to treat the quadriceps with a strength program, we suggest carrying out the treatment while sitting with the foot blocked, in order to avoid an involuntary leg extension during the contraction phase.

In all the programs with low intensity (massages, decontracting, drainage programs), comfort is the main aspect to be considered.

Electrode placement for Tens 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 is not included in the images represented, you can position the electrodes by forming a "square" on the aching area, as shown in the example below.





ELITE

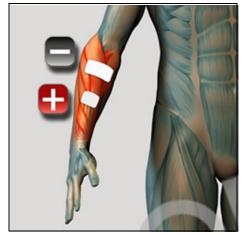
ELECTRODE PLACEMENT



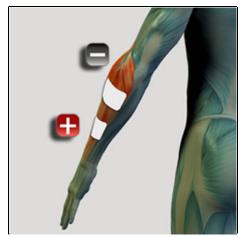
Biceps brachii muscle



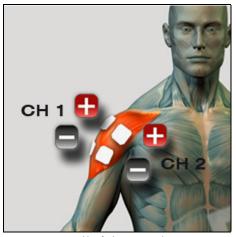
Triceps brachii muscle



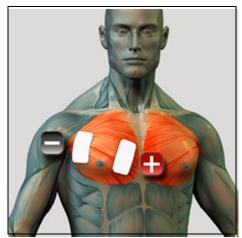
Flexor carpi muscle



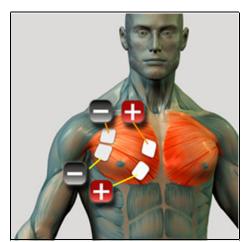
Extensor carpi muscle



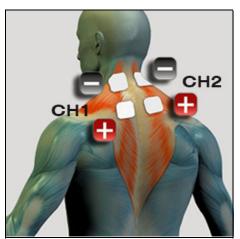
Deltoid muscle



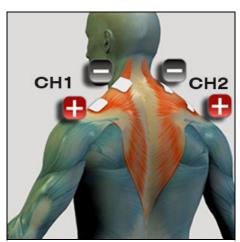
Pectoral muscle



Pectoral muscle



Trapezius muscle

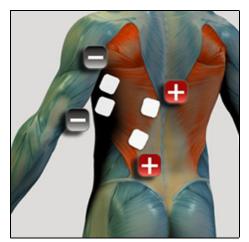


Trapezius muscle

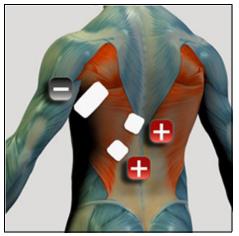




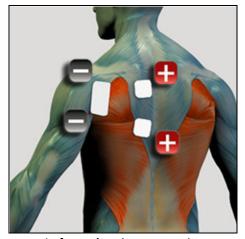
ELECTRODE PLACEMENT



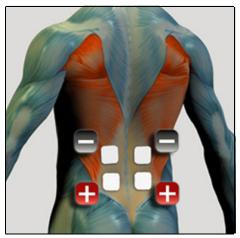
Latissimus dorsi muscle



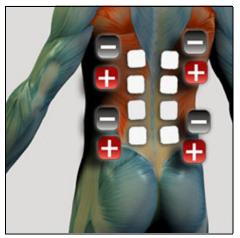
Latissimus dorsi muscle



Infraspinatus muscle



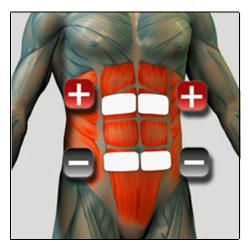
Lumbar muscles



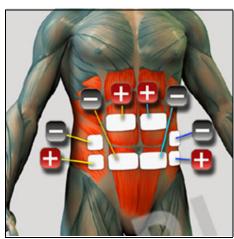
Lumbar/Dorsal muscles



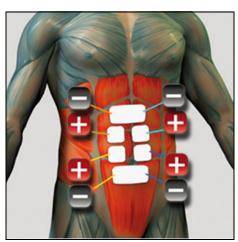
Abdominals



Abdominals



Abdominals

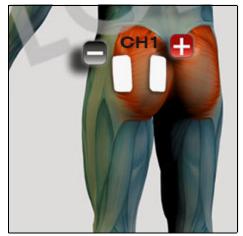


Rectus abdominis muscle

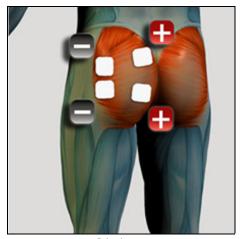


ELITE

ELECTRODE PLACEMENT



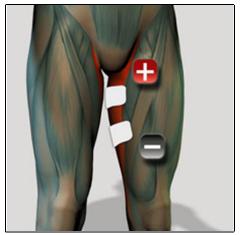




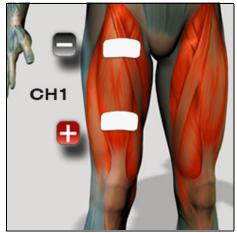
Gluteus



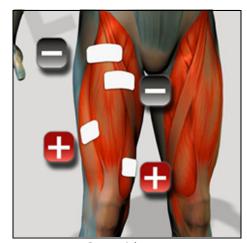
Biceps femoris muscle



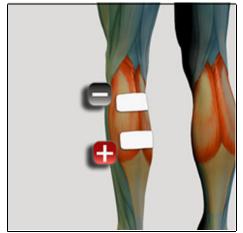
Adductors



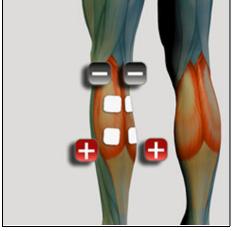
Rectus femoris muscle



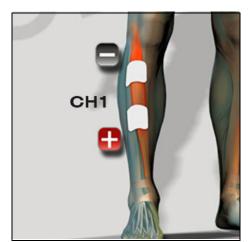
Quadriceps



Gastrocnemius muscle



Gastrocnemius muscle

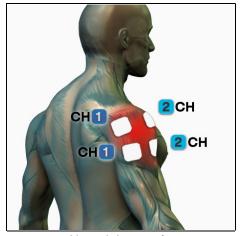


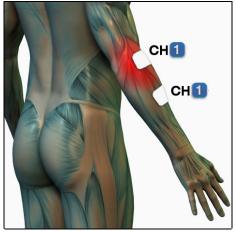
Tibialis anterior muscle

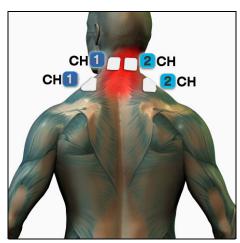




ELECTRODE PLACEMENT FOR TENS TREATMENTS



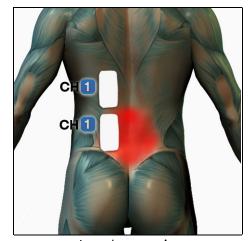


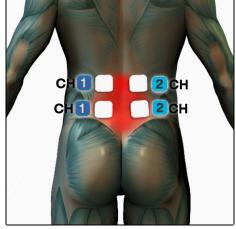


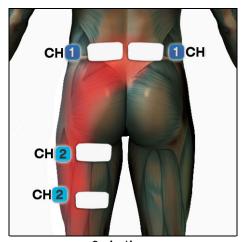
Shoulder pain

Elbow pain

Cervical pain



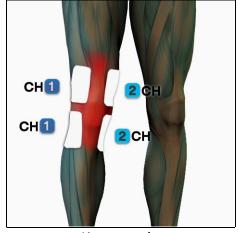


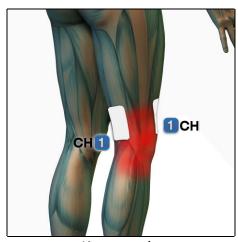


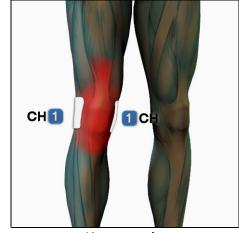
Lumbar pain

Lumbar pain

Sciatica







Knee pain

Knee pain

Knee pain



WARRANTY

The device includes a 24-month warranty for the first user, starting from the purchase date, which covers manufacturing flaws and defective materials, on condition that the device is used properly and kept efficiently. The warranty is limited to 12 months if the device is intended for professional use. Warranty coverage is limited in the following cases:

- Six (6) months for 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...
- The warranty does not include extendable accessories and materials such as electrodes, etc...

The warranty is valid and enforceable in the country where the product was purchased. If the product is purchased in a EU country, the warranty is valid in all member states.

The user has to comply with the following clauses for the warranty to be valid:

- 1. In case of repairs, the products and its accessories have to be sent in the original package at customer's expenses.
- 2. The warranty is valid only when the receipt or invoice of the product, indicating the purchasing date of the product, is enclosed.
- 3. Repairs will neither renew nor extend the warranty.
- 4. If repairs detect no flaws, the costs of the intervention will be charged anyway.
- 5. The warranty becomes void if 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 mishandling. The warranty does not cover damages caused during shipping by improper packages (see point 1).
- 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 reading user's instructions contained in the manual carefully and visit Globus website.

When returning your product for assistance, contact your dealer or contact Globus Customer Care. The manufacturer reserves the right to make changes without prior notice. The features and dimensions reported in this manual are not binding.



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 do not adhere to the skin anymore.

Where do the electrodes have to be placed?

The present manual contains a comprehensive electrode placement guide (it is not necessary to respect the polarities indicated): therefore, it is sufficient to comply with the instructions. However, the correct placement of the electrodes can be also determined empirically by using the Find Motor Point Pen: place the electrodes as indicated in the pictures in the present manual and then start the stimulation; move the electrode manually by sliding it along the muscle without removing it from the skin. You will notice a change in contraction according to the different positions of the electrode. Once located the point where the stimulation is higher, decrease the channel intensity to zero (0.0 mA), place the electrode again and increase the intensity gradually.

Use of Y cables. Do they permit to use more electrodes on the same channel?

They permit the use of more electrodes on the same channel, which allows, for instance, the stimulation of the vastus medialis and vastus lateralis of the quadriceps with one single channel. Do not use for medical applications.

Does the power decrease 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. However, it is fundamental to increase the intensity gradually, to observe the reaction of the muscle and to avoid keeping the limb completely outstretched. When in doubt, please contact a specialist.

Is it possible to use the electrostimulator during the menstrual 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?

No collateral effects regarding lactation have been observed so far. Yet, 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 will I see the first results?



ELITE

The aesthetic results of electrostimulation are always subjective. If performing the "Toning program" 3-4 sessions per week regularly, a noticeable result may be observed after 15 days. For Lipolysis and Drainage programs instead, 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 perform weekly?

For physical training, consult the program of weekly training in the Globus Personal Trainer. 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, whereas the treatments for Lipolysis and Drainage programs can be performed on a daily basis.



TABELLA 1

TABLE 1

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – EMISSIONI ELETTROMAGNETICHE – PER TUTTI GLI APPARECCHI ED I SISTEMI

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS – FOR ALL EQUIPMENT AND SYSTEMS

Il dispositivo ELITE è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dello ELITE deve garantire che esso viene usato in tale ambiente.

The ELITE is intended for use in the electromagnetic environment specified below. The customer or the user of the ELITE should assure that it is used in such an environment.

| Prova di emissione | Conformità | Ambiente elettromagnetico – Guida |
|---|------------|--|
| | - Comonina | 7 and one of our only ground of our our |
| Emissions Test | Compliance | Electromagnetic environment - Guidance |
| Emissioni RF | Gruppo 1 | Lo ELITE utilizza energia RF solo per il suo |
| RF emissions | Group 1 | funzionamento interno. Perciò le sue emissioni RF sono molto basse e |
| CISPR 11 | | verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini. |
| | | The ELITE uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| Emissioni RF | Classe B | Lo ELITE è adatto per l'uso in tutti i locali compresi quelli domestici e quelli collegati |
| RF emissions CISPR 11 | Class B | direttamente ad un'alimentazione di rete pubblica a bassa tensione che alimenta |
| OIOI IX II | | edifici usati per scopi domestici. |
| Emissioni armoniche | Classe A | The ELITE is suitable for use in all |
| Harmonics emissions | Class A | establishments, including domestic |
| IEC 61000-3-2 | | to the public low-voltage power supply |
| Emissioni di fluttuazioni di tensione/flicker | Conforme | network that supplies buildings used for domestic purposes |
| Voltage fluctuation/flicker emissions | | |
| IEC 61000-3-3 | | |



TABELLA 2 TABLE 2

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – IMMUNITÀ ELETTROMAGNETICA – PER TUTTI GLI APPARECCHI ED I SISTEMI

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS

ELITE è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dello ELITE deve garantire che esso viene usato in tale ambiente.

The ELITE is intended for use in the electromagnetic environment specified below. The customer or the user of the ELITE should assure that it is used in such an environment.

| Prova di immunità Immunity Test | Livello di prova IEC 60601 IEC 60601 test level | Livello di conformità Compliance level | Ambiente elettromagnetico – Guida Electromagnetic environment - Guidance |
|------------------------------------|---|--|---|
| Scarica elettrostatica (ESD) | ±6 kV a contact | ±6 kV a contact | I pavimenti devono essere in legno, calcestruzzo o in ceramica. |
| Electrostatic discharge (ESD) | ±8 kV in aria_ <i>air</i> | ±8 kV in aria_ <i>air</i> | Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa dovrebbe essere almeno 30%. |
| IEC 61000-4-2 | | | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Transitori/treni | ±2 kV per le linee di | ±2 kV per le linee di | La qualità della tensione di rete |
| elettrici veloci | alimentazione di | alimentazione di | dovrebbe essere quella di un |
| Electrical fast transient/burst | potenza_for power supply lines | potenza_for power supply lines | tipico ambiente commerciale o ospedaliero. |
| | ±1 kV per le linee di ingresso/uscita_for | ±1 kV per le linee di ingresso/uscita_for | Mains power quality should be that of a typical commercial or hospital |
| IEC 61000-4-4 | input/output lines | input/output lines | environment. |
| Sovratensioni | ±1 kV linea – linea | ±1 kV linea – linea | La qualità della tensione di rete |
| Surge | line-line | line-line | dovrebbe essere quella di un tipico ambiente commerciale o |
| | ±2 kV linea - terra line - earth | ±2 kV linea - terra line - earth | ospedaliero. |
| IEC 61000-4-5 | | | Mains power quality should be that of a typical commercial or hospital environment. |
| Buchi di tensione, | <5% U _T | <5% U _T | La qualità della tensione di rete |



| brevi interruzioni e variazioni di tensione sulle linee di ingresso dell'alimentazione Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | (>95% buco in_dip in U _T) per_for 0,5 cicli_cycle 40% U _T (60% buco in_dip in U _V) per_for 5 cicli_cycles 70% U _T (30% buco in_dip in U _T) per_for 25 cicli_cycles | (>95% buco in_dip in U_T) per_for 0,5 cicli_cycle $40\% \ U_T$ (60% buco in_dip in U_V) per_for 5 cicli_cycles $70\% \ U_T$ (30% buco in_dip in U_T) per_for 25 cicli_cycles | dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. Se l'utilizzatore dello ELITE richiede un funzionamento continuato anche durante l'interruzione della tensione di rete, si raccomanda di alimentare lo ELITE con un gruppo di continuità (UPS) o con batterie. Mains power quality should be that of a typical commercial or hospital environment. If the user of the ELITE requires continued operation during power mains interruptions, it is recommended that the ELITE be powered from an uninterruptible power supply or a battery |
|--|---|--|---|
| Campo magnetico a frequenza di rete (50/60 Hz) Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | <5% U _T (>95% buco in_dip in U _T) per_for 5 sec 3 A/m | <5% U _T (>95% buco in_dip in U _T) per_for 5 sec 3 A/m | I campi magnetici a frequenza di rete dovrebbero avere livelli caratteristici di una località tipica in ambiente commerciale o ospedaliero. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |

Nota_e U_T è la tensione di rete in c.a. prima dell'applicazione del livello di prova

 U_T is the a.c. mains voltage prior to application of the test level





TABELLA 4

TABLE 4

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – IMMUNITÀ ELETTROMAGNETICA – PER GLI APPARECCHI ED I SISTEMI CHE NON SONO DI SOSTENTAMENTO DI FUNZIONI VITALI

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING

ELITE è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dello ELITE deve garantire che esso venga usato in tale ambiente.

The ELITE is intended for use in the electromagnetic environment specified below. The customer or the user of the ELITE should assure that it is used in such an environment.

| | | T | |
|----------------------------------|---|-----------------------------------|--|
| Prova di immunità Immunity Test | Livello di prova IEC 60601 IEC 60601 test level | Livello di conformità Compliance | Ambiente elettromagnetico – Guida Electromagnetic environment - Guidance |
| | | level | |
| | | | Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati più vicino a nessuna parte dello ELITE compresi i cavi, della distanza di separazione raccomandata calcolata con l'equazione applicabile alla frequenza del trasmettitore Portable and mobile RF communications equipment should be used no closet to any part of the ELITE , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Distanza di separazione raccomandata |
| | | | Recommended separation distance |
| | | | $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$ |



| | | 1 | |
|---------------|------------------------|-------|---|
| | | | |
| RF condotta | 3 Veff_Vrms | 3 V | $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ da 80 MHz a 800 MHz |
| Conducted RF | | | $\lfloor E_1 \rfloor$ |
| | | | 80 MHz to 800 MHz |
| IEC 61000-4-6 | da 150 kHz a 80 MHz | | Г _ Л |
| | 150 kHz to 80 MHz | | $d = \left\lfloor \frac{7}{E_1} \right\rfloor \sqrt{P} \text{ da 800 MHz a 2,5 GHz}$ |
| | | | 800 MHz to 2,5 GHz |
| RF irradiata | 3 V/m | 3 V/m | |
| Radiated RF | | | |
| | | | |
| | | | |
| JEC 04000 4 3 | | | |
| IEC 61000-4-3 | da 80 MHz a 2,5 GHz | | |
| | 80MHz to 2,5 GHz | | |
| | | | ove P è la potenza massima nominale d'uscita del trasmettitore in Watt (W) |
| | | | secondo il costruttore del trasmettitore e |
| | | | <i>d</i> è la distanza di separazione raccomandata in metri (m). |
| | | | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter |
| | | | manufacturer and d is the |
| | | | recommended separation distance in metres (m). |
| | | | Le intensità di campo dei trasmettitori a RF fissi, come determinato da |
| | | | un'indagine elettromagnetica ^a del sito |
| | | | potrebbe essere minore del livello di conformità in ciascun intervallo di |
| | | | frequenza ^b |
| | | | Field strengths from fixed RF |





transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.

Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo:

Interference may occur in the vicinity of equipment marked with the following symbol:



Note s:

(1) A 80 MHz e 800 MHz; si applica l'intervallo di freguenza più alto.

At 80 MHz and 800 MHz, the higher frequency range applies.

(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.

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

Le intensità di campo per trasmettitori fissi come le stazioni base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM e FM e trasmettitori TV non possono essere previste teoricamente e con precisione. Per valutare un ambiente elettromagnetico causato da trasmettitori RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa uno ELITE , supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale del ELITE . Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione del ELITE .

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ELITE is used exceeds the applicable RF compliance level above, the ELITE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ELITE.

b L'intensità di campo nell'intervallo di frequenza da 150 kHz a 80 MHz dovrebbe essere minore di [V₁] V/m



Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V₁] V/m.

TABELLA 6 TABLE 6

- DISTANZE DI SEPARAZIONE RACCOMANDATE TRA APPARECCHI DI RADIOCOMUNICAZIONE PORTATILI E MOBILI E ELITE PER APPARECCHI O SISTEMI CHE NON SONO DI SOSTENTAMENTO DELLE FUNZIONI VITALI
- RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF
 COMMUNICATIONS EQUIPMENT AND THE ELITE FOR EQUIPMENT AND SYSTEM
 THAT ARE NOT LIFE-SUPPORTING
- ELITE è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore dello ELITE possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e lo ELITE come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.
- The ELITE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ELITE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ELITE as recommended below, according to the maximum output power of the communications equipment.

| Potenza di uscita massima del trasmettitore specificata | Distanza di separazione alla frequenza del trasmettitore (m) Separation distance according to frequency of transmitter (m) | | | |
|---|---|-----------------------------------|----------------------------|--|
| Rated maximum output power of transmitter W | Da 150 kHz a <i>_to</i> 80 MHz | Da 80 MHz a_ <i>to</i> 800 MHz | Da 800 MHz a_to 2,5 GHz | |
| 0,01 | 0,12 | 0,12 | 0,23 | |
| 0,1 | 0,38 | 0,38 | 0,73 | |
| 1 | 1,20 | 1,20 | 2,30 | |
| 10 | 3,80 | 3,80 | 7,30 | |
| 100 | 12,00 | 12,00 | 23,00 | |





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