CALMARE® PAIN THERAPY TREATMENT PROGRAM

User's Manual

Model: MC-5A

PAIN THERAPY MEDICAL DEVICE
FDA 510(k) Medical Device Clearance
CE Certified

Table of Contents

1. Indications for Use

The Calmare® Pain Therapy Treatment Model MC-5A is indicated for use in the symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain.

2. Device Description

The MC-5A is a 5-channel transcutaneous electrical nerve stimulator that provides stimulation based on a stored treatment program. Up to 5 pairs of electrodes can be placed on a patient's body to provide relief from chronic pain. It can be used by physicians, therapists, and trained medical personnel. Two microprocessors operate to ensure proper function of the unit and the treatment program. The treatment program operates automatically once the device is turned on and an output level is set on the amplitude control for each channel to suit the patient's sensitivity to the stimulation. In order to carry out correctly the treatment the operator must only position the electrodes. Electrode placement demands scrupulous compliance to the indicated methodology to identify the areas and immediate associated efficacy results. If the treatment is executed correctly, pain is usually zeroed out in real time regardless of intensity and pathology that generated it.

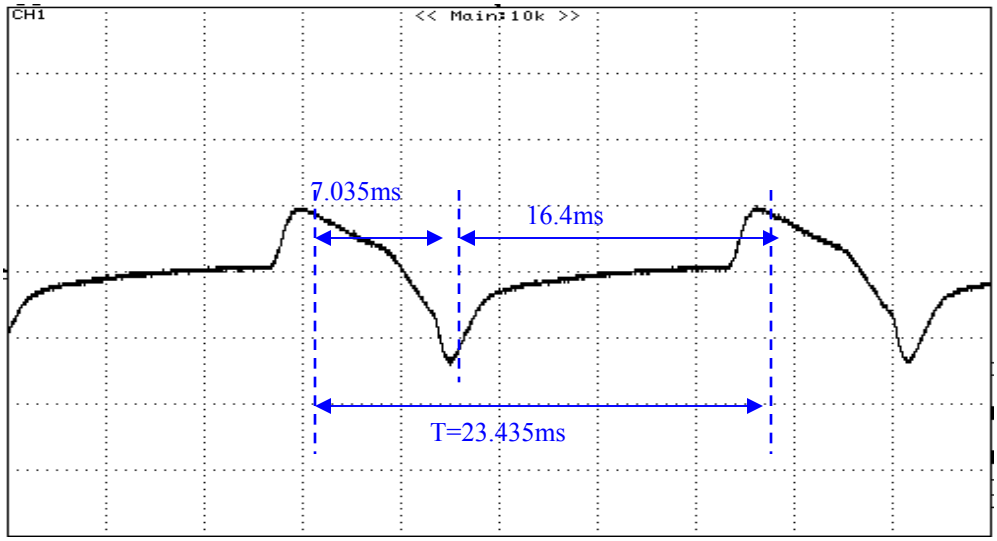
CAUTION:
Federal (USA) law restricts this device to sale by, or on the order of, a physician.

General Features

Power Supply	200-240V 50/60 Hz
Insulation	Class I
Applied part	BF
Waveforms	Artificial biopotentials modulated for digital synthesis with Scrambler codes (international patent) made of impulse sequences (strings) of max. amplitude 42 A C (dual -True RMS) on fictitious load of 10 kohm. Average wave train frequency < 80 Hz.
Protection	Double fuse on the network (2X 800 mA)
Overall absorption	0.3 A max.
Channels	5 independent
Decoupling	Separate output transformers for each channel
Electrode features	Disposable surface electrodes pretreated with GEL in fabric non fabric Ag/Ag CI

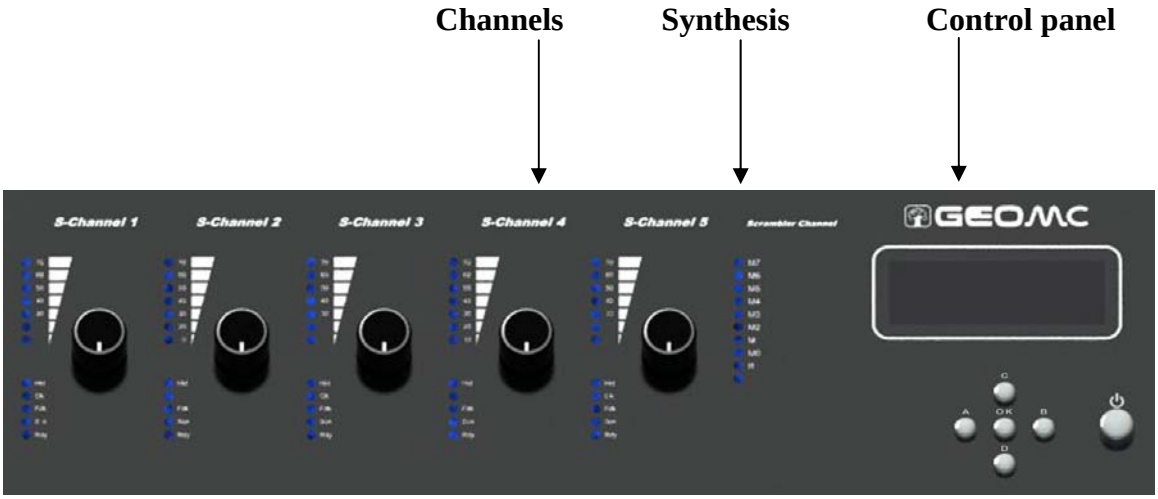
A representation of the Stimulation Waveform is found below:

500 Ω load



Output Voltage: 11.875 V p-p
Output Current: 23.78 mA p-p
Output Frequency: 43 Hz
Output Frequency Range: 42-53 Hz
Output Voltage Range: 11.875-118.75V p-p
Output Current Range: 11.875-23.78 mA p-p

2.1 Device Controls



- On/Off switch in the lower right hand corner marked “Power”.
- Front panel contains 5 knobs marked level which control the stimulation output of the treatment.

- Navigation buttons (A (left), B (right), C (up), D (down)-Ok) according to the layout displayed. They enable to modify the setup, to switch the end-of-treatment alert on and off, and to cancel a therapy.

2.2 Device Indicators

- The five channels are equipped with a series of warning lights which constantly monitor the proper operation of the device, correct cabling, and its functioning.

Channel Indicators

REF.	***DESCRIPTION***
Rdy	Indicates channel on hold (output level on zero) and ready to use
Scn	Service Monitor. Normally quickly flashing
Fdk	Normally on, if channel is up and running
Ok	Normally on, if channel is up and running
Hld	Normally quickly flashing, if channel is up and running
Meter	Displays the stimulus intensity applied (10/70)
Out	Connector of the output wire
Level	Manually regulates stimulus magnitude

2.3 Device Supplies

1.  10 Self Adhesive disposable surface electrodes pretreated with Gel
2.  5 Lead wires with connectors as shown
3. AC Power Supply – 220 Volt 50/60 Hz
4. Instruction Manual-instructions for use by physician or by trained medical personnel.

3. Warnings and Contraindications

3.1 Warnings

- The safety of the MC-5A device for use during pregnancy or labor has not been established.
- The MC-5A device is not effective for pain originating in the central nervous system. This includes headaches.
- The MC-5A device should be used only under the continued supervision of a physician, or trained medical personnel.
- The MC-5A device has no curative value.
- The MC-5A device provides a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Keep out of reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the device is in use.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- The use of this device is forbidden in the presence of inflammable anesthetic gases.
- Do not use this device to deliver a trans-thoracic stimulation. Because this device is capable of delivering a charge per pulse of 25 micro coulombs or greater, this may be sufficient to cause electrocution. It is recommended electrical current of this magnitude must be not flow through the thorax because it may cause a cardiac arrhythmia.

3.2 Contraindications

- DO NOT use on patients with metal implants such as pacemakers, automatic defibrillators, aneurysm clips, vena cava clips and skull plates.
- However, the MC-5A device CAN BE USED on patients with metal implants such as total knee, hip, shoulder and other joint replacements as

well as on patients with implanted pins, clips, screws, plates and cages used for orthopedic repair.

- DO NOT place Electrodes on the carotid sinus (front of neck) region of the body.
- DO NOT place Electrodes on the head.
- DO NOT use on patients prone to seizure (for example, epileptics).
- DO NOT use on undiagnosed pain.

3.3 Precautions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Effectiveness of the MC-5A device is highly dependent upon patient selection by a person qualified in the management of pain patients.
- Caution should be used when treating in the presence of the following:
  - Patients with a tendency to hemorrhage following acute trauma or fracture;
  - Painful area over the menstruating or pregnant uterus;
  - Areas of the skin that lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation, electrical conductive medium or stainless steel electrode array. Using an alternate electrode placement can usually reduce the irritation.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Avoid use of electrodes, conductive gels, lead wires, or accessories other than those supplied with the system or recommended by Competitive Technologies. The safety of other products has not been established and their use may result in skin irritations and burns beneath the electrodes.

4. Preparation for Use

- To correctly function in the required conditions of use, the device needs an electric system fitted with an automatic circuit breaker and earthing in the power point used for the system.
- MC-5A is a device specifically designed for hospital and outpatient facilities. Thus it easily transportable and mechanically robust.

4.1 Instructions for Use

1. In order to operate, MC-5A must simply be placed on a flat, stable surface.
2. After taking the cables out of the object compartment, the assembly will follow the steps illustrated in the power cabling picture below.

3. Position the power supply unit near the MC-5A. Plug the network cable between the adapter's empty socket and the power source (220/230 V 50/60 Hz) checking its regulatory compliance, in that it must include a grounded socket and automatic cut-out on the power line. The device must be compliant to increase its operational safety, moreover MC-5A, in order to avoid accidents, has a further set of independent protection measures, such

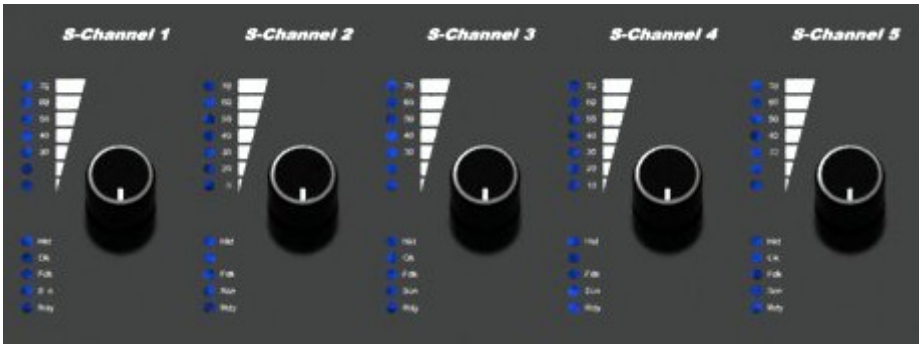
as low voltage picked up in the output by the power supply unit that drives another low tension power transformer/separator contained inside, plus an outbound transformer/separator that in a galvanic way isolates every channel from low voltage power supply and from other channels, rapid self-restoring fuses, and patient-insulation relays.

4. Connect electrode cables in the appropriate socket in every channel by gently inserting the plug, making sure it is snug and then locking the cable to the device by turning the metal collar clockwise until tight. At the ends of the cable there are 4 mm plugs usually inserted in electrode adaptors with button connection. If different types of electrode connections are required, do not modify the cable, but simply replace the adapter.

Picture of the cables (electrode side) and plugging into the Scrambler

5. Electrodes are inserted by simply pressing on the button connection.

6. Completely rotate counterclockwise the 5 knobs on the front panel.



7. Once these tasks have been completed, the device is ready for use and can be turned on. To modify the default operating parameters, it is possible to change the setup as explained in the “Setup” section.

4.2 Controls and Functions

Control Guide

The five channels are equipped with a series of warning lights to constantly monitor the proper operation of the device, correct cabling and it's functioning.

CHANNEL DESCRIPTION

REF.	*DESCRIPTION*
Rdy	Indicates channel on hold (output level on zero) and ready to use
Scn	Service Monitor. Normally quickly flashing
Fdk	Normally on, if channel is up and running
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Hld	Normally quickly flashing, if channel is up and running
Meter	Displays the stimulus intensity applied (10/70)
Out	Connector of the output wire
Level	Manually regulates stimulus magnitude

Description of Synthesis Module Panel

MC-5A is a system that uses two microprocessors operating in correlation, though operating independently. One is fully used to manage code synthesis. To verify the correct functioning of the module, it is sufficient to check warning lights M1 through M7. When the device is turned on, they light up in sequence, and then flash in sync, indicating the stand-by and correct program operation. During the therapy, at short intervals, warning lights go on and off in an apparently random manner. This activity enables the device to constantly monitor the correct operation of the module and program in a dynamic way.

4.3 Treatment Protocol

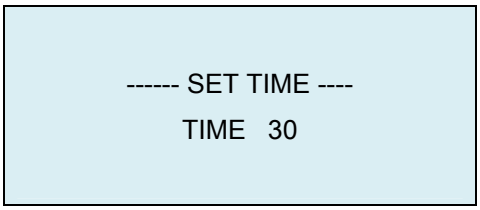
- To guarantee the most effective and lasting pain relief, the treatment should last 30-45 minutes, but it is possible to set up from 20 to 60 minutes.
- The treatment should include cycles (that can be repeated) of at least 10 treatments, to be carried out five times a week. In specific cases of terminal phase oncological pain (palliative cures) treatments should simply follow patient request when he/she feels the need.

4.4 Setup

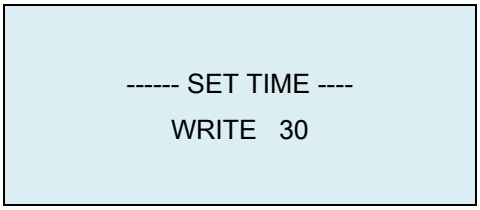
- If the Scrambler has not been set up, default options will be active to establish the treatment duration:

Therapy Duration

- 30 min. to 45 min. (it can be set from 20 to 60 min.)
- To intentionally change this Setup, press and keep pressed at the same time buttons C (Up) and D (Down), until the Setup menu appears.



- Using navigator buttons Up/Down the therapy duration can be modified. Then, by pressing OK, the duration is confirmed and the "Setup" is complete.



4.5 Placement of Electrodes

Each channel is connected to two electrodes through specific connectors, a red one and a black one. Excluding some specific cases, the electrodes must be placed slightly outside the pain area. It is necessary to identify each pain area before placing the electrodes. The best method is asking the patient to exert a light pressure on the skin with a finger until he/she finds the boundaries of the

pain area to be treated. If the boundaries of the pain area present impairing of sensitivity (paraesthesia, dysesthesia, numbness), electrodes should be placed beyond these boundaries, in the normal or sufficiently sensitive area closest to pain.

Note: In cases of painful anesthesia one of the two electrodes of the pair can also be placed in the area without tactile sensitivity, provided one is careful not to exceed in stimulation intensity, that the patient isn't able to correctly feel. Alternative signs of maximum stimulation intensity are absence of pain, beginning of muscle tinkling (if this were the case, stimulation intensity must be lowered), a clear and strong perception of the stimulation on the electrode placed in the area of normal sensitivity.

Overall, it is important to use areas of normal sensitivity to be certain synthetic information of "non-pain" generated by the device is correctly spread by the receptors of the engaged areas. Direct placement of electrodes inside dermotometrical areas of pain or other perception anomalies can reduce or even prevent synthetic information of "non-pain" to flow. Since the device uses to transmit A-Delta fibers and C fibers, thus directly pain ways, if information is degraded or doesn't flow correctly, the residual associated electric impulse can produce pain during or after intensity stimulation fine-tuning.

It is thus clear that the most important activity to guarantee the treatment's success is the correct identification of the pain area and possible perception anomalies. The description must also include pain that occurs only in certain positions or specific movements, that must be verified by asking the patient to recall the pain and clearly describe its boundaries. This activity should preferably be carried out during a short period of time, if necessary with rest breaks in order not to reduce the patient's compliance.

In very few cases, when there are no areas free from pain, you might find difficulty in placing the electrodes. This typically occurs in very extended face-pain, pudendal nevralgia involving rectum and perianal area, and hands and feet pain that extends to fingers and both sides.

In these cases, apart from the standard methodology one can use alternative strategies explained in the training courses and multimedia information aid, this however must be done after having a complete and clear understanding of the device's theory and practice. Bear in mind that these techniques are not easy to reproduce and must be tailored to patient's situation. Furthermore, 10 standard treatments are not sufficient and so a greater number of treatments is necessary. Overall, it is always preferable to use standard methodologies, which cover almost all possible different cases of pain.

Basic strategies for electrode placement

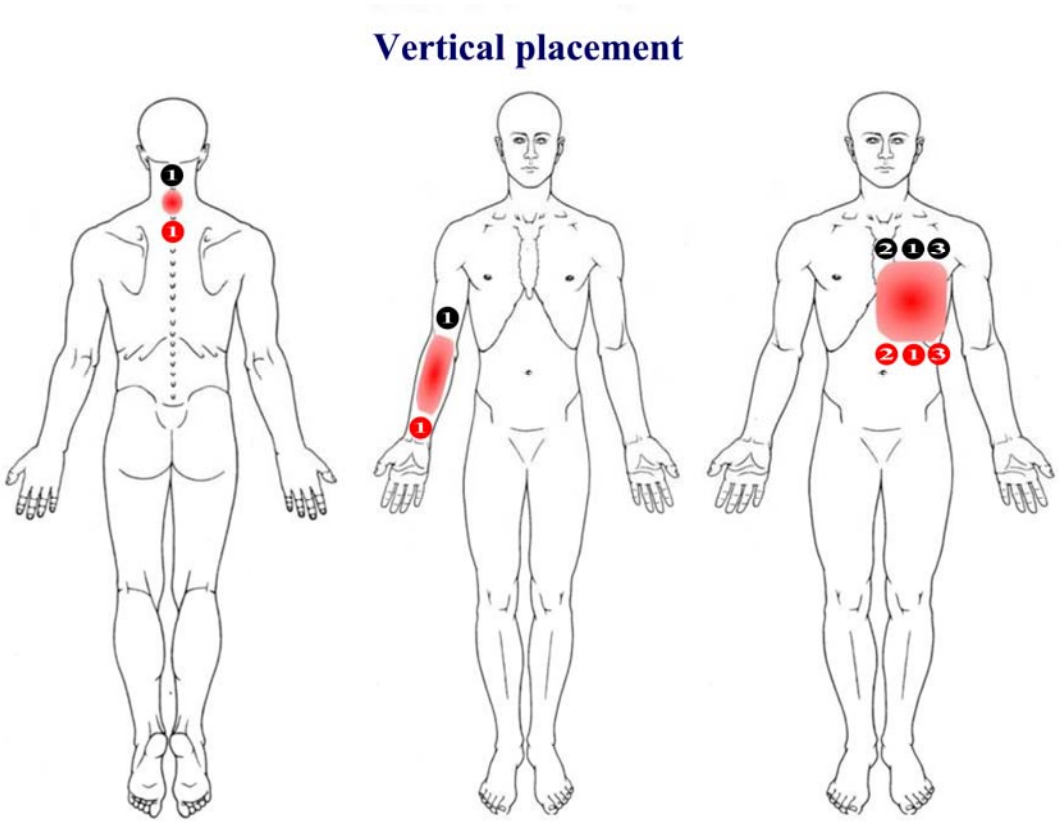
Each channel uses a pair of electrodes, one red one and one black one. In the example figures the number on each electrode enables to identify the pair that belongs to the same channel. All channels are perfectly interchangeable since they have the same functionality. Use only the channels that are really necessary. One doesn't need to use always all the five channels. In a small pain area, one channel can be enough. For more complex cases of pain usually all channels are needed.

When two or more channels are being used it is important to remember not to place beforehand all electrode pairs at the same time. This mistaken procedure can drastically reduce the device's efficacy and in some cases even lead to false results.

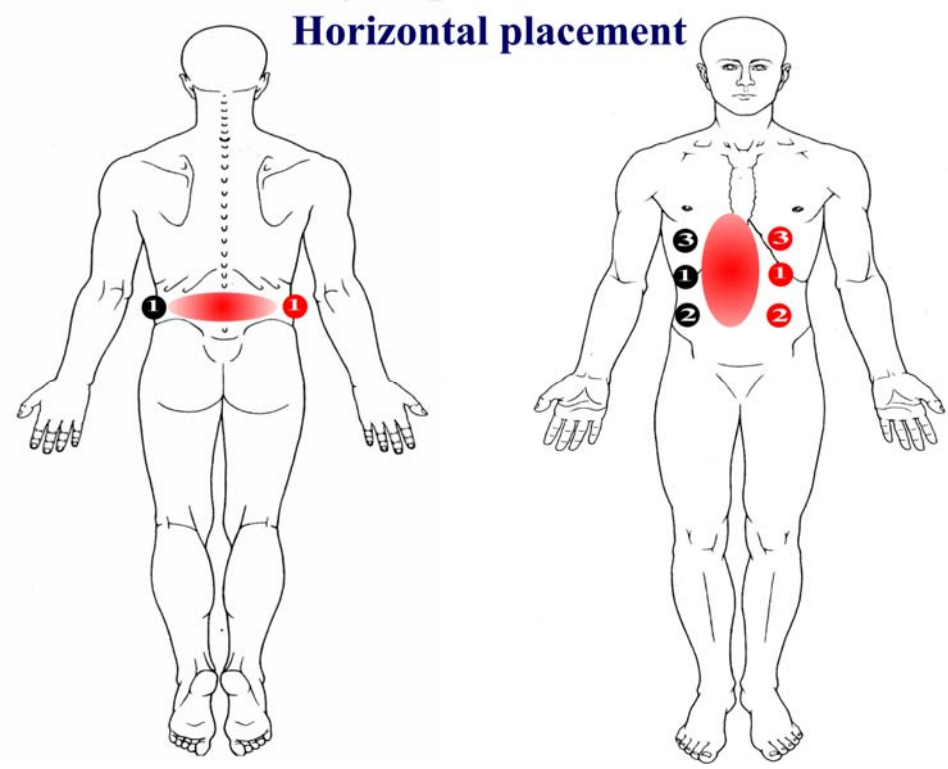
According to the correct procedure: first place a pair of electrodes, adjust the stimulation intensity, and only after having checked its analgesic efficacy on that specific pain area (zero or close to zero pain) go on and place the next pair of electrodes to cover the rest of the pain area following the same rules. The process must be carried out in an interactive way by using only the channels that are effectively needed to completely zero pain in the area.

Horizontal, vertical and crossed diagonal placements are possible depending on the size and area of pain. Usually in cases of large pain areas different types of placements are used together, in line with the geometry of the pain area and efficacy achieved during the placement of each pair of electrodes.

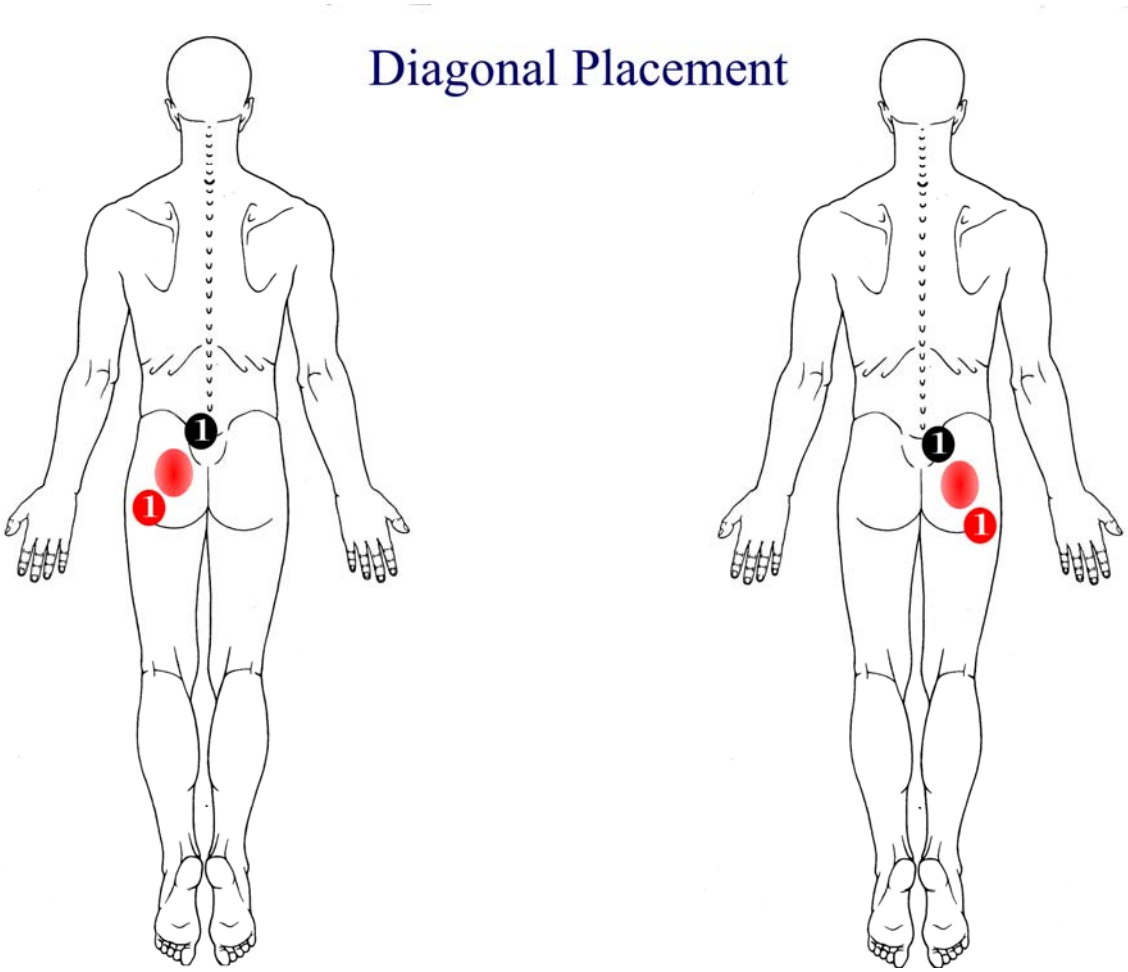
Important!... The position of pairs of electrodes with no analgesic efficacy must be changed (by either changing type of placement or moving then slightly outside the boundaries previously identified) until a desired effect is achieved. If after having tried different placements, rapid or immediate analgesia is not achieved after correct stimulation intensity adjustments, the pair of electrodes with no analgesic effect must be taken off.



Example of vertical placement (the numbers on the electrodes indicates the channel). *Electrode placement has merely a demonstrative purpose. Correct electrode placement is always identified by disappearance of pain in the area covered by the electrodes, manifested immediately or very rapidly after correct stimulation*



Example of horizontal placement (the numbers on the electrodes indicates the channel). *Electrode placement has merely a demonstrative purpose. Correct electrode placement is always identified by disappearance of pain in the area cover by the electrodes, manifested immediately or very rapidly after correct stimulation.*



Example of diagonal placement (the numbers on the electrodes indicates the channel). *Electrode placement has merely a demonstrative purpose. Correct electrode placement is always identified by disappearance of pain in the area cover by the electrodes, manifested immediately or very rapidly after correct stimulation.*

Please note that each placement starts always with the area where pain is more intense, imagining between the two electrodes a line passing at the core of this pain. Some types of pain respond better to a vertical placement, others to a horizontal or diagonal one, and some rare cases to crossed placements. It is possible to use any combination of these types of placement.

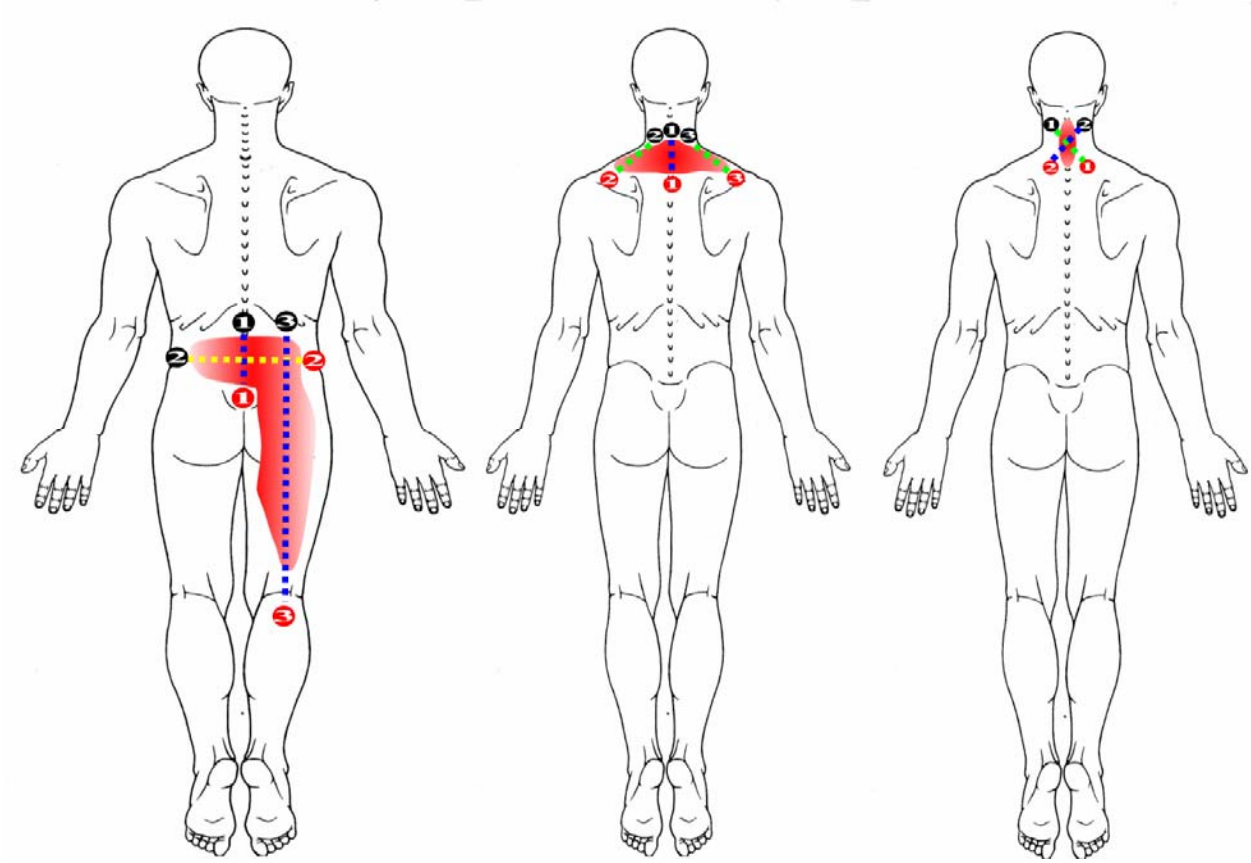
Please note the following regarding electrode placement:

- The red and black paired electrodes of each channel can be placed either

vertically or horizontally or diagonal. Normally, combination of placements will be used according to the geometry of the pain area (see example figure)

- All the vertical placements must have the same color electrodes of each channel on the same side. The same is true for horizontal placements. If this rule is not followed, the pain-killing effect drops. For example, if channel 1 and 2 are placed vertically, and the red electrode of channel 1 is placed on the top then the red electrode of channel 2 will have to be placed on the top. If the black electrode of channel 1 is placed on the top then the black electrode of channel 2 must be placed on the top.
- If the red electrode of channel 1 is placed on the right, the red electrode of channel 2 must also be placed on the right, and so on.
- Chronic pain should be treated using the electrode pairs of several channels. An example of chronic pain is low back pain. Usually the low back pain area must be treated with one or more channels (according to the extent of the pain area) with a horizontal placement. The part of pain that spreads to lower extremities passing through the gluteus, must be treated with a vertical placement. These different types of placements are used simultaneously during the same treatment session.

The following illustration is an example of placements that concurrently use more channels horizontally + vertically, or vertical + diagonal and crossed diagonal. The numbers on the electrodes correspond to the channel. For example, red 1 and black 1 are the electrodes that use channel 1, red 3 and black 3 are the electrodes connected to channel 3, and so on.



Example of horizontal + vertical, vertical+ diagonal, crossed diagonal placement (the numbers on the electrodes indicates the channel). *Electrode placement has merely a demonstrative purpose. Correct electrode placement is always identified by disappearance of pain in the area covered by the electrodes, manifested immediately or very rapidly after correct stimulation.*

Important Notes: when using Multiple Channels

a. Start by preparing to use only one channel according to the descriptions above. Once the connections have been made, the level is adjusted following the descriptions above.

b. In case the pain is reduced, but it is still present in some areas, while the first inserted channel is active, add another one to extend the treated area, following the same instructions. After having verified the pain relief of the new inserted electrode and channel, continue treatment until the complete disappearance of pain.

c. If the addition of electrodes and channels do not produce results, set the level to zero and use a different electrode placement repeating the operation of set-up and efficacy control.

d. Proceeding through a number of subsequent attempts, one can quickly understand when electrodes are correctly placed, because pain immediately disappears from the treated area. By using this feedback, it is possible to resolve the most complex situations thanks to the immediate response of full or substantial relief of the pain symptoms.

Additional Treatment Positioning

If it is difficult to identify areas free from pain to use for treatment, it is possible to use advanced positioning strategies that usually solve the problem. These strategies are explained during the training course and multimedia aid that integrates this manual.

- It is important to remember that the sign of correct treatment and electrode placement is zero pain (or very close to zero) in the treated areas.
- In cases when the pain occurs only in specific positions, make sure to position electrodes and monitor efficacy only when there is pain, otherwise the therapy cannot be effective. Once you are certain of the correct positioning, the patient can choose the position he is more comfortable with to continue the treatment.
- In difficult cases always try one channel at a time, checking its efficacy. If the time required for positioning reduces the length of the actual treatment, you should set to zero the levels of each channel without changing the positioning, then interrupt the therapy through the specific controls and start it on again to carry out a full treatment correctly. As an alternative, it is possible to previously set a longer treatment duration time that includes electrode placement and adjustment of the various channels.
- During the treatment the stimulation might be perceived with minor intensity because of the pain relieving effect. In this case it is necessary to increase the levels of the channels involved until the patient reports he clearly perceives the stimulation.

Stimulation level adjustment

- Verifying the correct placement is very easy and is done immediately by slowly and progressively increasing the stimulation level and asking the patient to indicate:
  a) if he feels a pain increase (excluding slight discomfort he might feel under the electrode). In the case when the patient feels a pain increase or other feeling of discomfort the stimulation level must be zeroed and electrodes must be re-positioned following the standard method.
  b) Starting from zero and slowly increasing the stimulation intensity, the patient will feel the first electrode as a feeling often described as a "sting" easily tolerable.
  c) when stimulation levels are increased, the patient will feel the second electrode. One of the two electrodes (of the same channel) will be always felt with less intensity.
  d) when the stimulation intensity is increased, the "sting" feeling on the two electrodes will be replaced by a pleasant tingling feeling. After the tingling feeling the analgesia effects starts, and will have to be optimized by adjusting the stimulation.
  e) lastly, fine-tuning is achieved by slowly increasing the stimulation intensity and asking the patient when he thinks he has reached the maximum threshold he can tolerate without feeling discomfort. Sometimes this threshold can correspond to a feeling of current flow between the two electrodes. If tolerable, this feeling is within the norm and favors a good analgesia even if the electrodes are not perfectly positioned.
  f) When conditions at point e) have been achieved, if the electrode positioning is correct, the patient will immediately refer he feels no pain in some or all the previous pain areas.
  g) If residual pain areas remain, another pair of electrodes must be placed by following the same procedure until pain is completely elimination (or close to zero). This procedure must be used in every area of pain.

  Warning 1. Pair of electrodes that are ineffective must never be used.
  Warning 2. A treatment that does not produce analgesia must be interrupted because apart from being of no use, it indicates the wrong electrode placement. Ineffective treatments must not be continued. They are of no use. In case of problems please contact someone who is more experienced on the method.
  Warning 3. In cases of chronic pain of stabilized neurological damage there is the possibility that during the first treatments the electrodes will have to be repositioned following the new areas of emerging pain. This is necessary when the old identified positions no longer produce the same effect. On the overall, this need is drastically reduced in the subsequent treatments.
  Warning 4. In cases of severe pain with neurological damage underway, electrodes must be positioned following the new emerging pain areas that can change with the damage evolution. This is always necessary when old identified positions no longer produce the same effect.
  Warning 5. Stimulation intensity in every treatment must always be fine-tuned

based on the procedure listed above. This level can change due to physiological factors (sweating, skin dryness etc.) also linked to favorable variations of pain symptomatology or better patient compliance.
Warning 6. It is not possible to treat patients without pain.
Warning 7. Intensity stimulation fine-tuning must be done slowly and continuously stopping, when you need to get information from the patients on the sensations he is feeling.

Therapy Duration

In most sessions, the treatment lasts 30 to 45 minutes but can run anywhere between 20 and 60 minutes in length.

Treatment Initiation

The treatment automatically starts when the level of any channel is raised, and automatically stops at the end of the duration previously set.

Unlike conventional transcutaneous electrical nerve stimulation (TENS), the treatment is completely automated and does not require setting up of individual wave parameters such as frequency, duty cycles, scanning etc. The only manual procedure required is the regulation of the stimulus magnitude, to be customized to the patient's individual sensitivity.

In case of power failure the treatment picks up again from interruption time, but it is also possible, if necessary, to manually cancel it and then restart the treatment.

4.6 Settings for Correct Usage

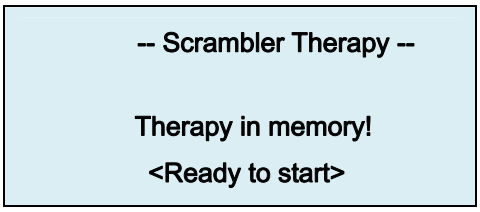
- Set the channels' amplitude to the maximum value of the threshold of tolerance of individual patients. Do not exceed this threshold, as it does not improve the therapy.
- The ideal setup threshold is the one that enables the subject to feel stimulation on both electrodes of every active channel that does not provide discomfort.
- If more than one channel is used, set one channel at a time, and after having verified its pain relieving efficiency, proceed to setting the other channel.
- If the electrode placement is not effective and there is no affect, the channel must be zeroed, and the electrodes' position must be changed and the setup operation repeated.

- Discontinue use if the signal is felt only on one of the two electrodes. Check the position to ensure correct operation.
- Ensure that the patient does not have pain or discomfort under the electrodes or in the pain area. If this where the case the electrodes must be repositioned slightly away from the area chosen to eliminate the problem and achieve the analgesic effect. Failure to follow these indications can lead to undesirable effects during or after the treatment.
- Impulses emitted by the device frequently vary and the patient must be informed that he will often have various sensations at the electrode site.
- Always check analgesic effect of each pair of electrodes before placing the following one.

4.7 Activation of a Therapy

When turning MC-5A on, check if there are any previously stored treatments that have not been completed. This happens when the device is turned off before the treatment has been completed which will be automatically stored. When the device is turned back on, the memory enables an automatic restart of treatment from where it was interrupted. This is useful when the shutdown is erroneous, or due to a power outage.

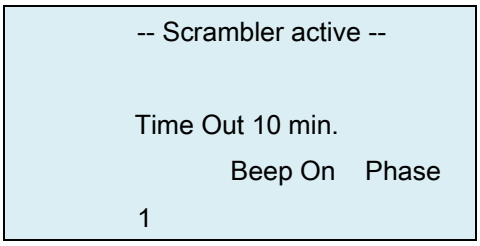
If this occurs, a clear message is displayed, and there are two options. The first one is to restart the therapy in memory, following the same steps as previously described start a new treatment. This is useful if the treatment was interrupted for a short-term power outage, and the same patient must complete the treatment. In this case, the start time is the moment when the treatment was interrupted. The second option is to cancel the therapy in memory. To do so, one must push the B (right) and A (left) navigation buttons simultaneously for a few seconds at the same time. Once the therapy is cancelled, the warning message will disappear.



1. Before increasing the level of the channel, ensure the cable is connected correctly between the channel output and the electrodes. Generally it is always necessary to put a drop of GEL for the ultrasounds in the conducting

part of the electrode if it is not spongy. If the conducting part is spongy, the GEL is not strictly necessary. It is however suggested to apply it to improve conduction and reduce slight skin reddening. The GEL must never be spread on the electrode's sticky area, since this might determine a poor electric contact or possible detachment from the skin. NEVER REUSE used electrodes.

2. Very Slowly rotate the channel control handle until a relay click is heard and service information will be shown on the display. The warning signal **OK** will appear, while **RDY** will turn off. If this does not occur, the cable connection is incorrect and the level control must be completely rotated counterclockwise to set the channel to stand-by mode. Subsequently, the entire operation must be repeated after completing the positioning checks.
3. Continue to very slowly rotate the intensity control knob until the patient feels the stimulation from the channel that is being used. **It is normal to perceive one of the two electrodes more intensely**. Once the treatment is underway, the Display will show the time left to the end of the treatment, the activation of the end-of-therapy alert sound, and the current status of the therapy.



4. This procedure must be repeated for each channel used after having checked analgesic efficacy (complete or almost complete disappearance of pain) of the one that has just been adjusted.
5. For the correct functioning the warning lights **Ok, Fdk** must be consistently lit. The letters **Scn** and **Hld** will flash consistently.
6. During the set up, if the warning light **Ok** turns off, an alert signal is immediately displayed with a "feedback absent" message. The turning off of the warning light Ok can be caused by:
   - Broken or short-circuited cable
   - Cable disconnected from the electrodes
   - Bad electrode contact
   - Insufficient or deteriorated gel on the electrodes.

-- Feedback absent --

1 – Zero levels

2 – Check cables

3 – Restart

7. To stop the alert signal, set the outbound levels of all channels to 0. After having checked and corrected the anomaly, the channel can be again used without having to cancel and restart the treatment.

8. During normal operation, the level bar will show a different position according to the power requested, the rotation of the level control dial, and the limit set for power supply under safety conditions, that is automatically adjusted. This leads to a non-linearity between the increase in the rotation of level control and the indication of actual power delivery, influenced by the feedback loop of the circuits controlling the forwarding of Scrambler codes and skin impedance. The ratio of the level control rotation and Meter indication varies from patient to patient.

Please note that this difference from patient to patient depends on the area that is being treated, individual sensitivity, and alterations in pain perception

Caution: If an electrode or cable is disconnected, do not place it again on the patient before having set to zero the channel intensity level or related alarm. If you do not follow this procedure, the patient may feel a slight shock that is minor in nature.

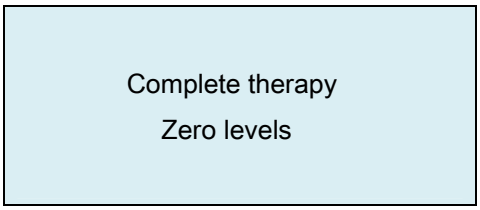
Even when the protection system is on, remember it will always react a couple of seconds after a connection fails.

Operational Checks

The patient should feel immediate pain relief and no stimulation trouble during use. Any discomfort should be evaluated immediately. If the correct treatment areas are difficult to find, a response that produces a partial pain-relief is acceptable, as long as the patient doesn't feel a stimulation discomfort. In the treatments that will follow electrode placement must be improved to achieve complete zero pain during the treatment. If pain is not zeroed during the treatment, results after a treatment cycle, or analgesia duration between one treatment and the following one, will certainly be statistically worse than expected.

4.8 Interruption of a Therapy

- To cancel a therapy, press the two navigator A (right) and B (left) buttons at the same time and wait for the message confirming the interruption.
- The treatment must not be interrupted by turning off the device; otherwise the subsequent treatment could start from the amount of time that hasn't been used in the previous one.



Activate/Deactivate END-OF TREATMENT ALERT SOUND

During active therapy, press the OK button in the middle of the navigator to switch on (**Beep On** the display), or switch off (**Beep off** on the display) the end-of-treatment sound alert.

This command is stored every time the treatment is turned on. Every time the device is turned on, the Beep on/beep off status will be the same that was more recently set and stored.

Please note that for safety reasons it is impossible to disable the sound alerts.

4.9 Frequent Errors

Experience gathered throughout the years analyzing the usage of the device by operators with different degrees of expertise, enabled to identify most common errors. The simplest one is failing to adjust the intensity, when during the

treatment the stimulation fades. This further adjustment is generally needed only after the first minutes of the treatment, when the analgesic effect stabilizes in depth.

Another typical mistake is that of failing to follow changes in the pain area during the progressive treatments, and always maintaining the same electrode placement. This is possible only if the analgesic effect remains constant, if this where not the case, electrodes must be re-positioned in the new treatments by always following the general procedures. Usually the need to re-position the electrodes ends after the third treatment.

Another mistake is to continue the treatment when the patient perceives a pain increase. In these cases the treatment must be interrupted, and the pair of electrodes that generate the problem must be re-positioned.

Almost all the new users of the device make the mistake of thinking they can exploit acupuncture points. Electro-acupuncture is simply acupuncture, and results different from the ones of acupuncture cannot be expected, even by using inappropriately the Scrambler for this purpose. This approach will have a relevant negative impact on the quality and quantity of the results. Some positive results are only due to the fact that some points by chance correspond to receptors useful for the treatment.

The treatment's stability and progression speed can be worsened by the use of anticonvulsants, the only molecule that theoretically and experimentally is unfavorable in association with this device. In general, concurrent use of high dosage anticonvulsants will produce a rapid relapse. At the same time, anticonvulsants must be phased down to avoid rebound effects. Whenever possible the patient should be weaned from anticonvulsants before beginning a Scrambler Therapy treatment. As an alternative the dosage should be gradually reduced during the treatment.

We must always remind patients that Scrambler Therapy produces analgesia, not anesthesia. This is the reason why an acute pain produced by trauma cannot be eliminated beforehand. Patients with herniated disc or similar problems must always remember that pain disappearance does not entail cure of the organic damage. Performing risky movements in the documented organic damage, can reactivate the pain sympthomatology, and one cannot exclude a possible transitory acute pain determined by a wrong movement.

Many think that it is useful to use all available channels to surround pain and activate them without checking their real effect step by step as prescribed. In fact this approach will drastically reduce success possibilities, and can also lead to a pain increase after the treatment.

If you understand the way Scrambler Therapy works the concept is quite simple.

A pair of electrodes that does not produce analgesia impairs the correct functioning of other electrodes pairs, reducing their efficacy A pair of electrodes that produces pain can, during the treatment, be covered up (concealed) by another pair of electrodes that produce analgesia. At the end of the treatment, however, this problem easily emerges. A pair of electrodes that produces analgesia cannot produce pain, thus proving its correct positioning.

Anomaly due to frequent errors and its solution

- **Anomaly:** pain increase during and after the treatment. This event normally occurs when, during the treatment, fibers still connected to pain are involuntarily stimulated. It can also occur when stimulations areas had altered functionality (par aesthesia, disesthesia, numbleness).
  Symptom: during stimulation, the channel produces analgesia, but the patient feels an unpleasant anomalous feeling or the feeling of pain in other areas increases.
  Mistaken action: cover induced pain by inadequate placement with other electrodes.
  Correct action: zero the channel that produces pain and modify the electrode placement until analgesia in the interested area is produced. It is usually sufficient to slightly distance electrodes from the pain area.

- **Anomaly**: pain appears in different areas from the initial ones. This might be caused by movements that were impossible before due to initial pain, therefore new pain resulting from mechanical causes linked to increased mobility.
  Symptom: very acute pain in areas different from the initial ones.
  Mistaken action: failure to inform the patient that the treatment does not modify organic injury, and warn him against performing risky movements.
  Correct Action: inform the patient to cautiously control his movements also if after the treatment he/she feel no pain.

- **Anomaly:** new lower intensity pain emerges in area different from the initial ones, while main pain is correctly reduced. In general this pain has always been there but was masked by more intense main pain.
  Symptom: less intense pain in areas close but different from initial ones.
  Mistaken action: none.
  Correct action: treat also newly emerged pain.

- **Anomaly:** there are problems in placing electrodes to eliminate pain. The areas free from pain are not sufficient to find optimal electrode placement.
  Mistaken action: perform an inefficient treatment.
  Correct action: place electrodes to reduce at least the intensity and extension of the pain area. If there is at least a partial analgesia in the treated area, increase the stimulation (avoiding it being too discomforting for patient) to increase the number of recruited augmenting the area and degree of analgesia. Improve the electrode placements in the following sessions.

- **Anomaly:** the previous treatment same analgesic effect does not occur even if electrodes have been placed in the same position.
  Mistaken action: electrodes have been positioned "by memory" without checking each channel's efficacy.
  Correct action: each new application requires electrode placement depending on the current feeling of pain and its evolution. One must always be guided by the pain area and patient's answers, never by a fixed pattern even if it was previously successful.

- **Anomaly**: pain intensity curve of each treatment does not progressively decrease in line with statistic expectations even if the treatment's analgesic response is effective. Treated pathology does not justify this behavior.
  Mistaken action: none if during the treatment pain is correctly zeroed.
  Correct action: if anticonvulsants are used, gradually start weaning away from them. In this case, a longer treatment cycle is needed, following the weaning away. Verify other possible causes (pathologies not diagnosed at the beginning or wrongly diagnosed, emergence of new complications etc.)

5. Troubleshooting

Problem	***Solution***
It is impossible to turn the Scrambler on	Verify the connection to the power supply unit and the electrical power network. If all is in place, call for assistance.
The Scrambler starts at a different time from the one set.	The previous therapy has not been completed. Cancel the therapy and restart the procedure.
The line error message appears.	Check the cabling and verify the presence of faulty cables, wrongly connected electrodes, without or with insufficient GEL. If the problem persists, call for assistance.
One or more channels do not work	Turn the device off and on once again. If the problem persists, call for assistance.
In the ready position, synthesis module's vertical warning signals don't flash.	Turn the device off and on once again. If the problem persists call for assistance.
During treatment, synthesis module's vertical warning signals are fixed.	Turn the device off and on once again. If the problem persists call for assistance.

6. Maintenance

The system, with the exception of a routine check of the cables to be connected to the patient, does not require ordinary maintenance and/or calibration operations.

No fluids should be used to clean the outside area of the device, but simply a

simple duster. If necessary, for a thorough cleaning use a cloth soaked in alcohol, after having disconnected the device from the main power supply.

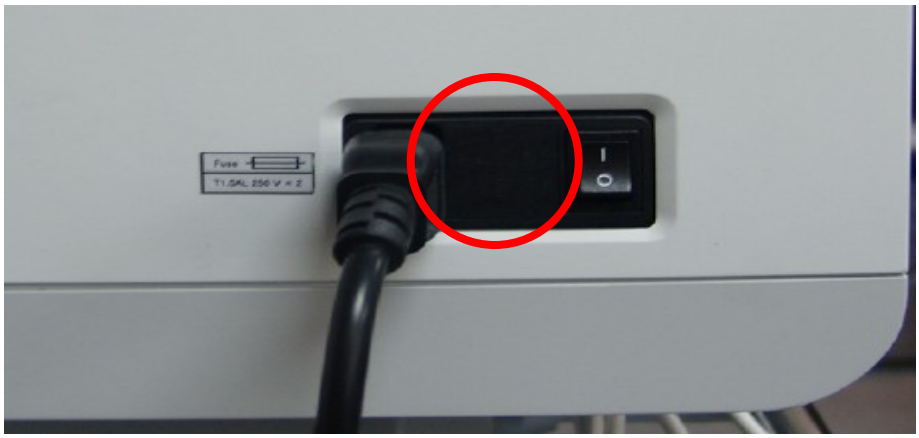
After cleaning, carefully check whether the wiring for correct operation has loosened and if so, tighten the cables.

6.1 Fuse Replacement

The device has two fuses on the network that, whenever necessary, must be replaced with others of the same value (0.8A). The user can change only one of the two fuses that are accessible from outside. If the inner fuse must be replaced, the manufacturer must be called to send an authorized technician to carry out the procedure.

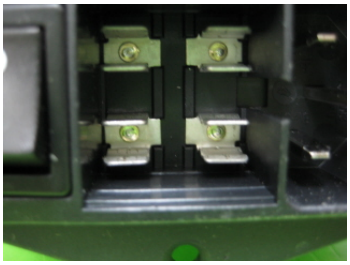
To replace the external fuse, inside the mains cable tray, it is necessary to:

1. Disconnect the mains cable, if present.
2. Push the unlock lever and extract the fuse-holder, with the use of a small flat blade screwdriver.

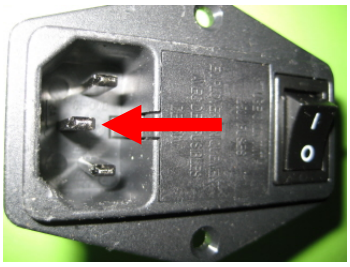


Remove the fuse and replace it with one of the same value.

Please use the extra fuse located under the operating one if necessary.



3. Re-insert the new fuse in the fuse-holder in the appropriate lock. Correctly position the entire fuse-holder in its slot, gently pushing it in until it locks.



6.2 Cleaning and Disinfection

MC-5A is not a sterile device. Please follow the following:

- Disposable electrodes to be replaced after every treatment
- Periodic cleaning of connection cables to patient with commercial non-oily disinfectants
- The device should not be used on open wounds or in contact with other biological fluids.

7. Technical Support

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