

# CALMARE™ Model MC-5A

## Non-Invasive Pain Therapy Treatment



Scrambler Technology

## User's Manual

International Version

CE 0470

## Table of Contents

<i>Item</i>	<i>Page</i>
1. Indications for Use.....	3
2. Device Description.....	3
2.1 Device Controls .....	4
2.2 Device Indicators .....	5
2.3 Device Supplies .....	5
3. Warnings and Contraindications.....	6
3.1 Warnings.....	6
3.2 Contraindications.....	6
3.3 Precautions.....	7
4. Preparation for Use.....	7
4.1 Instructions for Use.....	8
4.2 Controls and Functions .....	10
4.3 Treatment Protocol.....	11
4.4 Setup .....	11
4.5 Placement of Electrodes.....	11
4.6 Settings for Correct Usage.....	16
4.7 Activation of a Therapy .....	16
4.8 Interruption of a Therapy .....	19
5. Troubleshooting.....	20
6. Maintenance.....	20
6.1 Fuse Replacement.....	20
6.2 Cleaning and Disinfection.....	22
7. Technical Support.....	22

## 1. Indications for Use

The Calmare Therapy 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 Calmare Therapy MC-5A is a 5-channel transcutaneous electrical nerve stimulator which 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, nurses, 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. The electrodes are placed in tandem at points around the area where pain is experienced to provide relief.

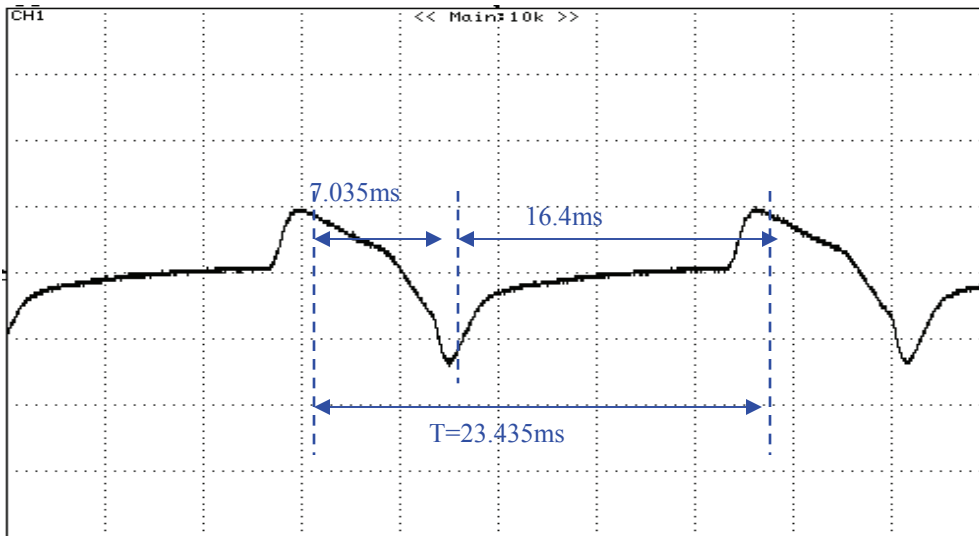
### **CAUTION:**

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

### **General Features**

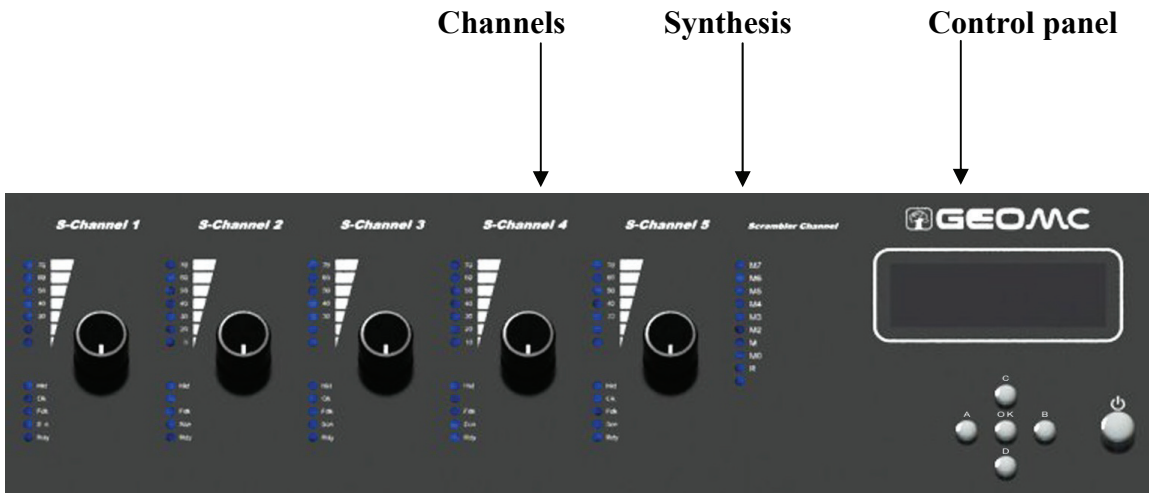
Power Supply	200-240V 50/60 Hz
Insulation	Class I
Applied part	BF
Waveforms	Artificial biopotentials modulated for digital synthesis with Scrambler codes (international patent) made of impulse sequences (strings) of max. amplitude 42 A C (dual -True RMS) on fictitious load of 10 kohm. Average wave train 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 Cl

A representation of the Stimulation Waveform is found below:  
 500  $\Omega$  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

<i>REF.</i>	<i>DESCRIPTION</i>
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 snap 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 Calmare MC-5A device for use during pregnancy or labor has not been established.
- The Calmare MC-5A device may not be effective for pain originating in the central nervous system. This includes headaches.
- The Calmare MC-5A device should be used only under the continued supervision of a physician, or trained medical personnel.
- The Calmare MC-5A device does not cure the underlying cause of the pain.
- The Calmare 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.

#### **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 Calmare 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 unless under direct supervision of the clinician.

- 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 Calmare 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. The irritation can usually be reduced by using an alternate electrode placement.
- 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. It's easily transportable and mechanically robust.



#### 4.1 Instructions for Use

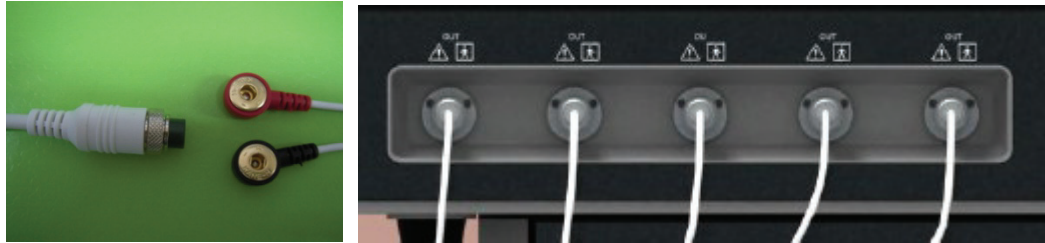
1. In order to operate, the MC-5A must be placed on a flat, stable surface.
2. Cable assembly will follow the steps illustrated in the power cabling picture below.



3. Position the power supply unit near the MC-5A. Plug the network cable into 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 MC-5A must be compliant to increase its operational safety to avoid accidents. The MC-5A 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/separators contained inside, plus an outbound transformer/separators 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

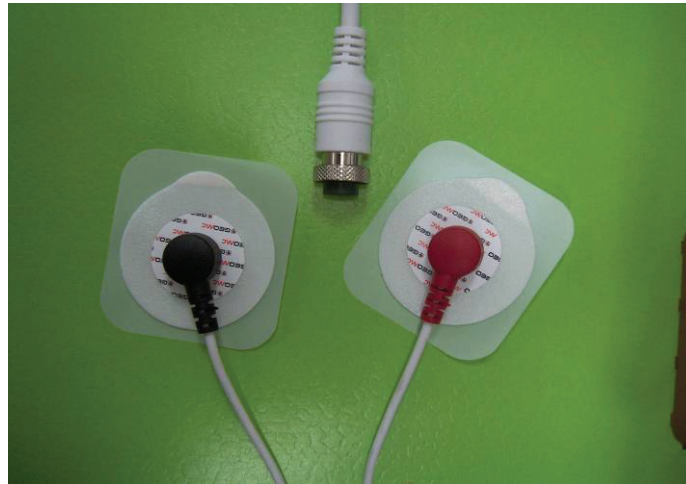


of each cable there are 4 mm plugs with a snap-type connection. If different types of electrode connections are required, do not modify the cable, but simply replace the adapter.

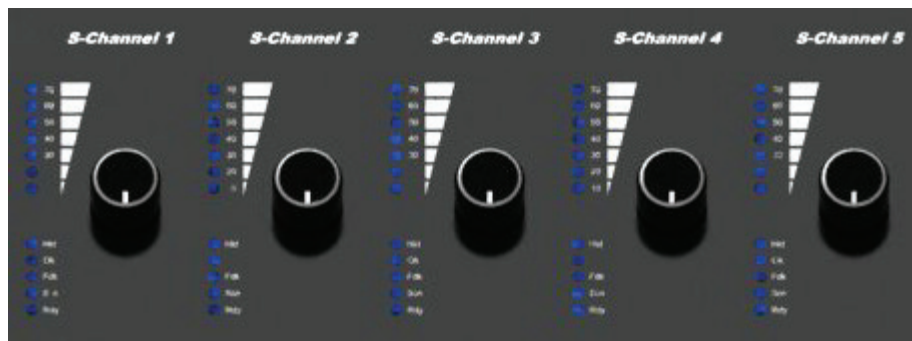


**Picture of the cables (electrode side) and plugging into the MC-5A**

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

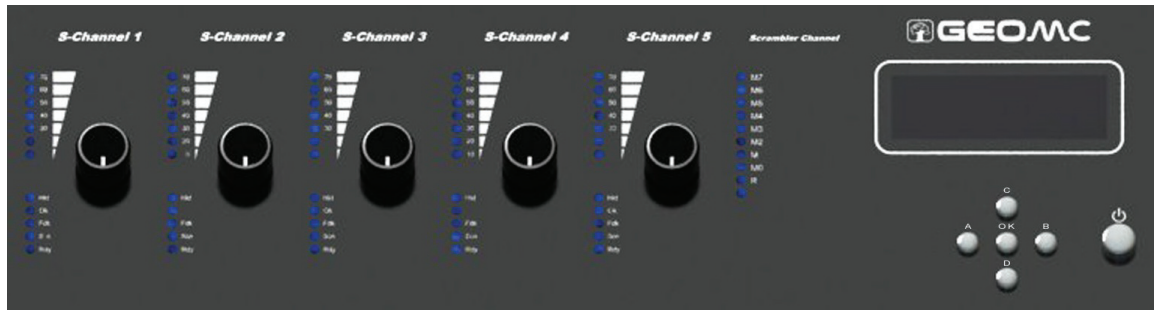


6. Completely rotate the 5 knobs counterclockwise on the front panel.



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 5 channels are equipped with a series of warning lights to constantly monitor the proper operation of the device, correct cabling and its functioning.

### CHANNEL DESCRIPTION

<i>REF.</i>	<i>DESCRIPTION</i>
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

### 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 a 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

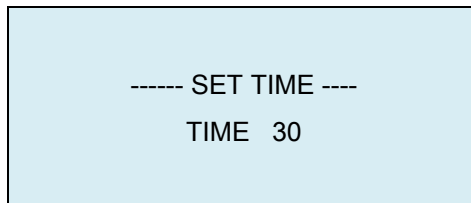
- To guarantee the most effective and lasting pain relief, the treatment should last 30-45 minutes, but it is possible to set up from 20 to 60 minutes.
- The treatment should include cycles (that can be repeated) made up of 10 treatments at least, to be carried out at a frequency of 5 times a week.

### 4.4 Setup

- If the MC-5A has not been set up, default options will be active that establish the treatment duration:

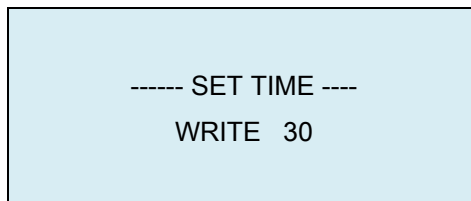
#### **Therapy Duration**

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



----- SET TIME ----  
TIME 30

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

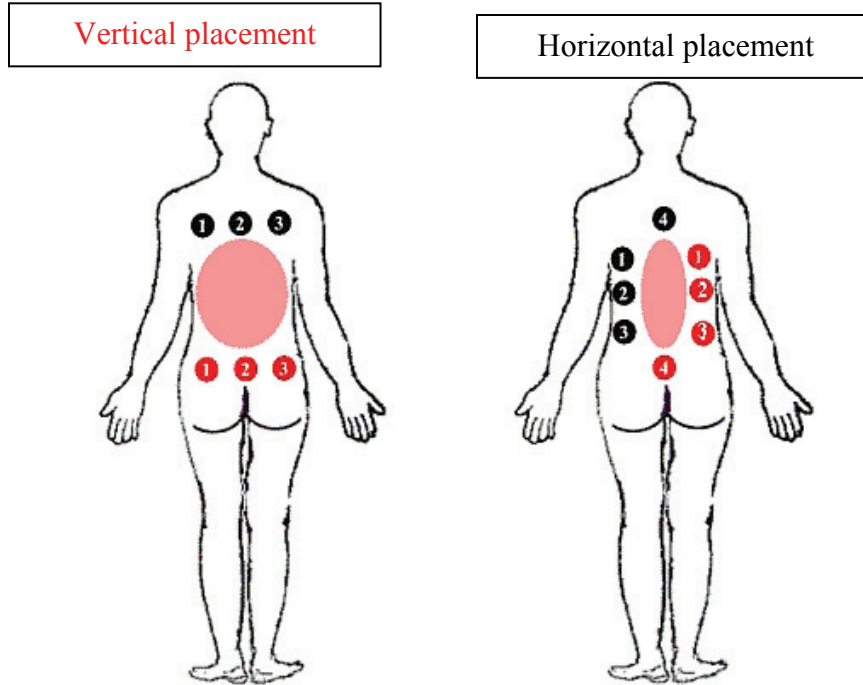


----- SET TIME ----  
WRITE 30

### 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 to ask 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.

Each channel's two electrodes (red and black pair) must be positioned 2 to 3 inches away from the area of pain as shown in the figure below:



**Figure 1. Example Electrode Patients  
(the numbers on electrodes indicate the channel)**

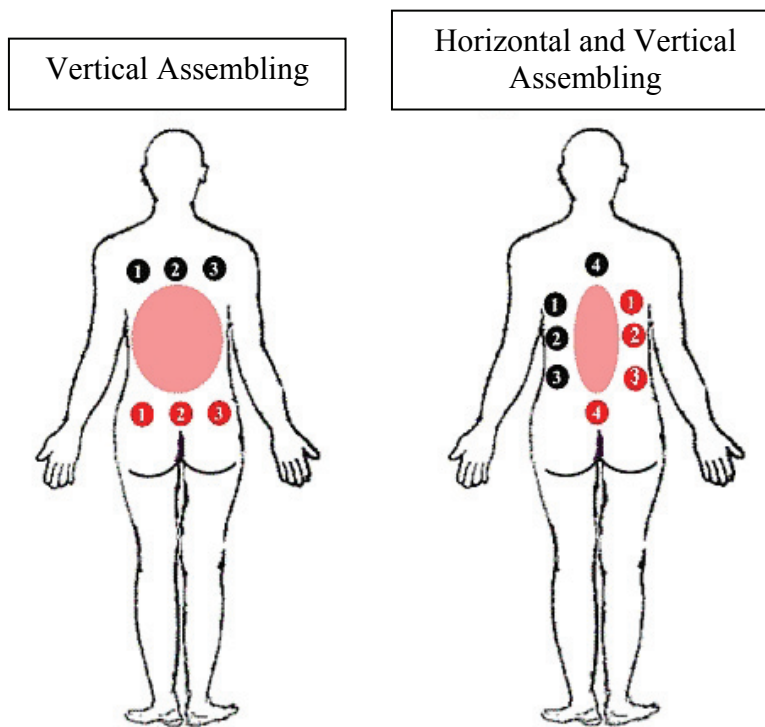
Please note in the above example that in the first case, the electrodes have been placed vertically and in the second case, the electrodes are placed horizontally passing through the center of the pain area. The positions of the electrodes correspond to some forms of pain that respond better to a vertical placement and other forms of pain that respond better to horizontal placement. Please note the following regarding electrode placement:

- The red and black paired electrodes of each channel can be placed either vertically or horizontally.
- 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 two types of placements are used simultaneously during the same treatment session.

The following illustration (Figure 2) is an example of placements that concurrently use more channels vertically or horizontally + vertically. 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.



**Figure 2. Example of Multiple Channel Use**

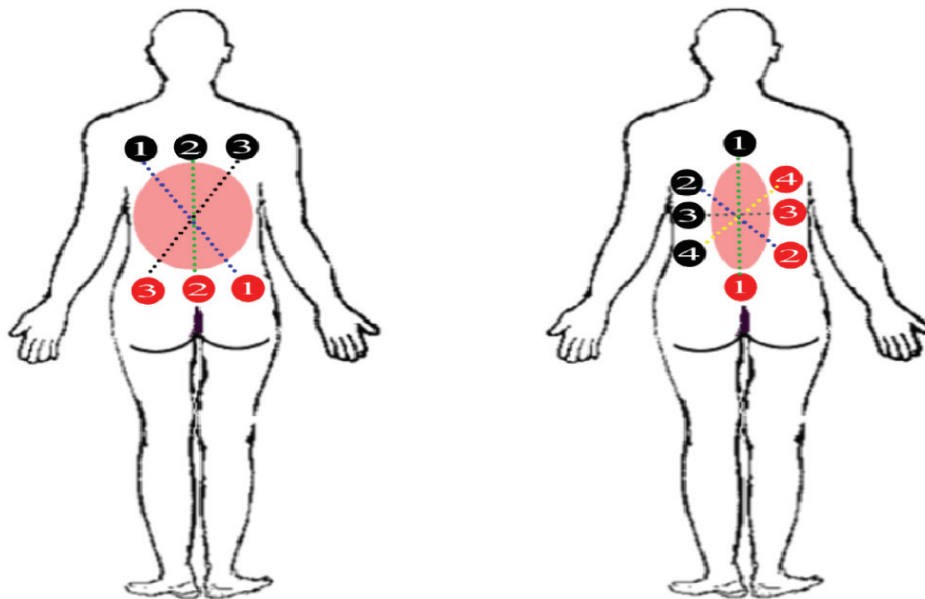
### **Important Notes When using Multiple Channels**

- 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 pain free areas useful for treatment, it is possible to use advanced positioning strategies that usually solve the problem. A strategy is to use contralateral areas. Please see the examples below in Figure 3.



**Figure 3. Additional Placement Positioning**

**Note: All described positioning types are valid for any area of the body.**

In the example on the left, a diagonal (X-shaped) is used for positioning channels 1 and 3, and channel 2 vertically. The figure on the right demonstrates the diagonal placement of channels 2 and 4, and channel 1 placed vertically and

channel 3 horizontally. These examples provide various positions that cover the pain area in several directions. These examples require the use of multiple channels. When using these examples please remember the following:

- It is important to remember that the sign of correct treatment and electrode placement is the reduction of pain in the areas involved.
- 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 the levels of each channel to zero without changing the positioning, then interrupt the therapy through the specific controls and start it on again to carry out a full treatment correctly.
- 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/she clearly perceives the stimulation.

### **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.

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 set to zero, 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. In this 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/she will often have various sensations at the electrode site.
- Ensure that positioning is correct from an electronic and operational point of view by asking the patient whether he/she is able to feel the pain after every channel has been turned on. If the patient responds with any answer other than no, please set the channels to zero and begin again.

#### **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 shutdown 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.

-- Calmare Therapy --  
  
Therapy in memory!  
<Ready to start>

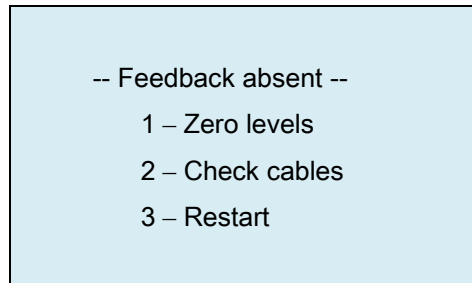
1. Before increasing the level of the channel, ensure the cable is connected correctly between the channel output and the electrodes. Even if not necessary, it is preferable to put another drop of gel on the conductive part of the electrode placed on the skin. NEVER REUSE patient electrodes.
2. Very 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 control knob intensity 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.

-- Scrambler active --  
  
Time Out 10 min.  
Beep On Phase 1

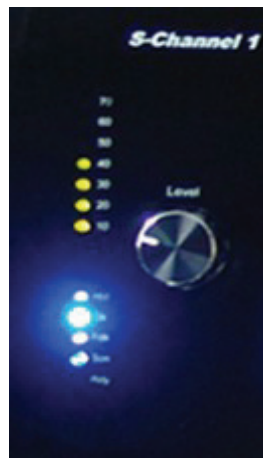
4. This operation needs to be repeated for each channel used.
5. For the correct functioning the warning lights **Ok**, **Fdk** must be consistently lit. The letters **Scn** and **Hld** will flash consistently.
6. During the set up, if the warning light **Ok** turns off, an alert signal is

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.



7. To stop the alert signal, set the outbound levels of all channels to zero. 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 meter 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.

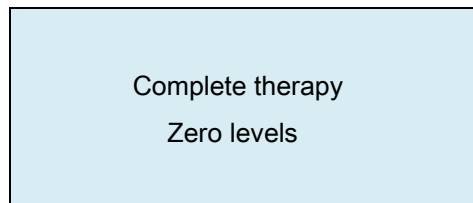
Even when the protection system is on, remember it will always react a couple of seconds after a connection fails.

### **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 does not feel a stimulation discomfort.

#### **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 has not 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** 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.**

## 5. Troubleshooting

<b><i>Problem</i></b>	<b><i>Solution</i></b>
It is impossible to turn the MC-5A on.	Verify the connection to the power supply unit and the electrical power network. If all is in place, call for assistance.
The MC-5A 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 two 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 do not 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.

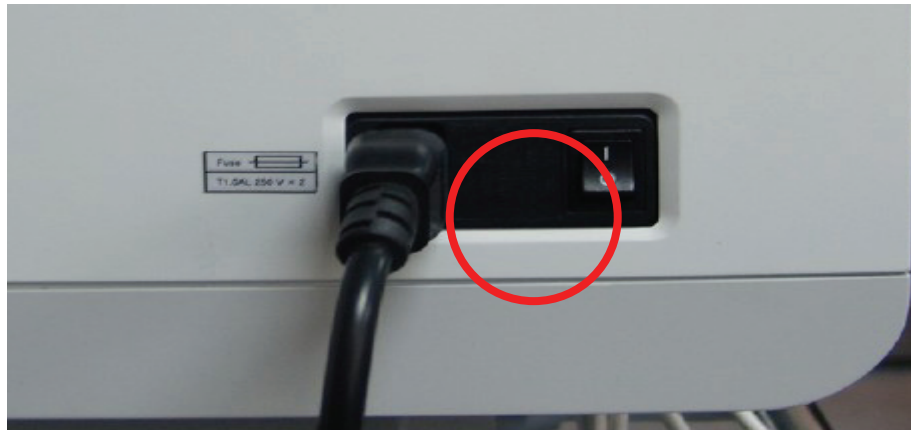
After cleaning, carefully check whether the wiring for correct operation has loosened and if so, tighten the cables.

### 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:

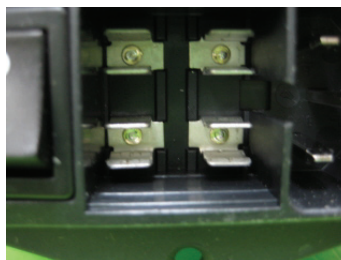
1. Disconnect the main cable, if present.
2. Push the unlock lever and extract the fuse-holder, with the use of a small flat blade screwdriver.



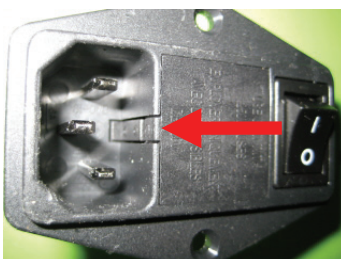
Remove the fuse and replace it with one of the same value.



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**

GEOMC Co., Ltd.  
17F Samsung Fire B/D, #1329 Seocho-2Dong,  
Seocho-Gu, Seoul, Korea  
Tel: +82-2-586-6871  
Fax: +82-2-3486-0445

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