



Empi Elite™

COMPLETE ELECTROTHERAPY SYSTEM



USER'S MANUAL

Read this manual carefully before operating the Elite

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MOTION IS MEDICINE™

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Forward



Read this User Manual carefully before you start using your Empi Elite device. The manufacturer strongly recommends careful reading of the “Warnings and Cautions” and “Safety Guide” Sections of this User Manual. www.djoglobal.com website helps you for your first steps with the device.

How to get help

To order the Empi Elite device for your patients, contact either your local Empi/DJO Global representative or Empi Clinic Services at 800.325.5663

Empi, Inc.
205 Hwy 22 East
Clear Lake, SD 57226 USA

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Warnings and Cautions



Contraindications

Do not use the Empi Elite if you have one or more of the following medical conditions:

1. This device must not be used on persons with cardiac pacemakers, defibrillators, or other implanted electronic devices.
2. Cardiac demand pacemakers.
3. Epilepsy.
4. Following acute trauma or fracture.
5. Critical ischemia of lower limbs.
6. Abdominal or inguinal hernia.
7. Cancerous lesions.
8. Pregnancy (do not use on abdominal region).
9. Serious arterial circulation problems in lower limbs.
10. Serious infectious disease.

11. Heat or fevers.
12. Capillary fragility or capillary damage.
13. Sensitivity problems or unable to express yourself.

Osteosynthesis equipment

The presence of osteosynthesis equipment (metallic equipment in contact with the bone: pins, screws, plates, prostheses, etc.) is not a contraindication for the use of Empi Elite programs. The electrical currents of the Empi Elite are specially designed to have no harmful effect on osteosynthesis equipment.



Warnings

- Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).
- The Empi Elite is to be used under the supervision of a physician.
- Never use it in ways other than recommended in the “Operating Instructions” Chapter of this User Manual.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied:
 - Over the carotid sinus nerve, particularly in patient with a known sensitivity to the carotid sinus reflex.
 - Transthoracically (across the thoracic cavity or chest) in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
 - Transcerebrally (across the brain). The effects of stimulation on the brain are unknown.
- On the neck or mouth. Contractions and spasms of the muscle of the airway may cause difficulty in breathing or close the airway passages. Stimulation on the neck may also have adverse effects on the heart rhythm or blood pressure.
- Over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Over, or in proximity to, cancerous lesions.
- Over pulled muscles. Using the stimulator on a previously extended muscle may

further full such muscle. The higher the stimulation intensity, the higher the risk to further over-extend such muscle.

- Do not use the Empi Elite on persons with capillary fragility to avoid excessive capillary damage.
- Some persons may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- Never carry out an initial stimulation session on a person who is standing. The first five minutes of stimulation must always be performed on a person who is sitting or lying down. In rare instances, people of a nervous disposition may experience a vasovagal reaction. This is of psychological origin and is connected with a fear of the muscle stimulation as well as surprise at seeing one of their muscles contract without having intentionally contracted it themselves. A vasovagal reaction causes heart to slow down and blood pressure to drop, which can make you feel weak and faint. If this does occur, all that is required is to stop the stimulation and lie down with the legs raised until the feeling of weakness disappears (5 to 10 minutes).
- Never allow movement resulting from muscular contraction during a stimulation session. You should always stimulate isometrically; this means that the extremities of the limb in which a muscle is being stimulated must be firmly fixed, so as to prevent the movement that results from contraction.
- Do not use accessories manufactured by other companies on the Empi Elite. DJO, LLC is not responsible for any consequence resulting from using products manufactured by other companies. The use of other accessories or cables may result in increased emissions or decreased immunity of the Empi Elite.
- The Empi Elite should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the unit should be observed to verify normal operation in the configuration in which it will be used.
- Do not use the Empi Elite within X meter (see EMC table) of short wave or microwave devices as this could alter the currents generated by the stimulator. If you in any

doubt as to the use of the Empi Elite close to another medical device, seek advice from the manufacturer of the latter or from your doctor.

- Do not use the Empi Elite if you are connected to a high-frequency surgical instrument as this could cause skin irritation or burns under the electrodes.
- Do not use the Empi Elite stimulator in areas where unprotected devices are used to emit electromagnetic radiation. Portable communications equipment can interfere with electrical medical equipment.
- Do not use the Empi Elite in water or in a humid atmosphere (sauna, hydrotherapy, etc.).
- Do not use the Empi Elite in oxygen-rich environments.
- Do not use in areas where there is a risk of explosion.
- Sudden temperature changes can cause condensation to build up inside the stimulator. To prevent this, allow it to reach ambient temperature before use.
- Do not disconnect any leadwires during a session while the stimulator is switched on. Switch the stimulator off first.
- Never connect leadwires to an external power supply. There is a risk of electric shock.
- Never recharge the stimulator without first disconnecting the leadwires.
- Never use the Empi Elite or the charger if it is damaged (case, cables, etc.) or if the battery compartment is open. There is a risk of electric shock.
- Disconnect the charger immediately if the Empi Elite “beeps” continuously, if there is abnormal heating or smell, or if smoke comes from the charger or the Empi Elite.
- Do not recharge the battery in a confined space. There is a risk of fire or electric shock.
- Keep the Empi Elite and its accessories out of reach of children.
- Do not share electrodes with other persons. All users should have their own set of electrodes to prevent undesirable skin reactions.
- Do not allow any foreign bodies (soil, water, metal, etc.) to penetrate the Empi Elite, the battery compartment and the charger.

- Do not use the Empi Elite while driving, operating machinery or during any activity in which involuntary muscle contractions may put the user at risk of injury.
- Do not use the stimulator at altitudes of over 9,842 feet (3,000 meters).



Precautions

1. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
 2. Safety of powered muscle stimulators for use during pregnancy has not been established.
 3. Use with caution on patients in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;
 - b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus;
 - d. Over areas of the skin which lack normal sensation;
 - e. Suspected or diagnosed heart problems;
 - f. Suspected or diagnosed epilepsy.
 4. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.
 5. Using the Empi Elite on muscles gradually to avoid over extend muscles. A gradual regimen is recommended.
 6. Use only with the, battery charger, lead wires and electrodes supplied by Empi. Skin irritation may occur in persons with particularly sensitive skin or lacking normal sensitivity.
- Precautions when using the electrodes
 - Only use electrodes supplied by Empi. Other electrodes may have electrical properties that are unsuitable for the Empi Elite stimulator.

- Do not use electrodes with a surface < 19 cm², as there will be a risk of suffering a burn injury. Caution should always be exercised with current densities > 2mA/cm².
- Always turn off the stimulator before moving or removing any electrodes during a session.
- Do not place the electrodes in water.
- Do not apply solvents of any kind to the electrodes.
- For best results, wash and clean the skin of any oil and dry it before attaching the electrodes.
- Attach the electrodes in such a way that their entire surface is in contact with the skin.
- For obvious reasons of hygiene, each user must have his or her electrode set. Do not use the same electrodes on different people.
- Never use a set of adhesive electrodes for more than 15 sessions as their bonding power deteriorates over time and optimal contact is very important for both user comfort and efficacy.
- Some people with very sensitive skin may experience redness under the electrodes after a session. Generally, this redness is completely harmless and disappears after some time (from a few minutes, up to a few hours). Never start another stimulation session in the same area, if the redness is still visible.

Adverse Reactions

1. Skin irritation and burns beneath the electrodes have been reported with the use of stimulation electrodes applied to the skin.
Note: Some people with very sensitive skin may experience redness under the electrodes after a session. Generally, this redness is completely harmless and disappears after some time (from a few minutes, up to a few hours). Consult your doctors if the redness of the skin does not disappear after a few hours.
2. Headache and other painful sensations have been reported during or following the application of electrical stimulation applied to the head, face, and near the eyes.

Where Never to Apply the Electrodes



- On the head or any area of the face.



- On the neck or any area of the throat.



- On both sides of the thorax simultaneously (front and back sides, or lateral sides).



- On, or in the vicinity of skin lesions or eruptions of any kind (wounds, swelling, burns, irritation, eczema, etc.).
- Over the abdominal region during menstruation periods.
- On skin areas lacking of normal sensation.

Indications for Use

Intended Use

The Empi Elite is intended for the following conditions:

- Muscle reeducation
- Prevention or retardation of disuse atrophy
- Relaxation of muscle spasms
- Increasing local blood circulation
- Maintaining or increasing range of motion

Usage Guidelines

The use guidelines presented in this section should be considered as general rules. For all programs, it is recommended that you read the usage information and advice presented in chapter VI "Programs" carefully. **IF YOU ARE UNSURE, CALL YOUR MEDICAL PROFESSIONAL OR EMPI REPRESENTATIVE BEFORE PROCEEDING.**

1. Choice of the Appropriate Muscle Program

The choice of a program is determined by the injured body parts or joints. The appropriate muscle stimulation programs (e.g., Massage, Strength, or Endurance) and frequency of the program(s) are determined by the medical professional. Consult your medical professional to be sure to understand the Empi Elite.

2. Planning of Stimulation Sessions

Your Medical Professional will instruct you on a protocol (intensity, electrode placement, number of times per day and per week) to follow in order to use the Empi Elite most effectively.

3. Electrode positions

For optimal results, use the electrode positions recommended by your medical professional. Please also refer to the pictures and pictograms shown in back of the manual. Each stimulation cable has two poles:

A positive pole (+) = red connection

A negative pole (-) = black connection

An electrode must be connected to each pole.

Note: It is possible and normal to have an electrode arrangement that leaves one electrode connection free from a cable. Each lead should be connected to the proper electrode (positive and negative ends).

Depending on the characteristics of the current, efficiency can be optimized in certain programs. When working with a muscle stimulation program (program involving muscle contractions), it is important to connect the electrode to the positive pole (red connection) and place the positive electrode on the motor point of the muscle.

It is crucial to choose the right size electrodes (large or small) and correctly position these on the muscle group you want to stimulate to ensure the efficiency of the program. Therefore, always use the size of electrodes shown in the pictures. Unless you have other specific instructions by your medical professionals, always follow the placement directions in the pictures.

Where necessary, look for the best possible position by slowly moving the positive electrode over the muscle until you find the point that will produce the best contraction or the most comfort for you.

4. Stimulation positions

This position will vary depending on the position of the electrodes, the muscle group you wish to stimulate, and the program you are using.

For programs involving powerful muscular contractions (for example: Strength and Endurance programs), the muscle should always be stimulated in an isometric fashion. It is therefore strongly recommended that you must keep the knee bent at 90 degrees and the foot flat on the ground). In this way, you provide maximum resistance to the movement and prevent any shortening of the muscle during the contraction, which could create cramp pains and serious stiffness after the session.

For the MESSAGE program, which does not involve powerful muscular contractions, position yourself as comfortably as possible.

5. Adjusting stimulation energies

In a stimulated muscle, the number of recruited fibers depends on the stimulation energy. For programs involving powerful muscular contractions (for example: Strength and Endurance programs), you must therefore use the stimulation energy level (programmed up to 999) at the limit that you can endure, in order to recruit the maximum number of fibers. Always consult your medical professionals.

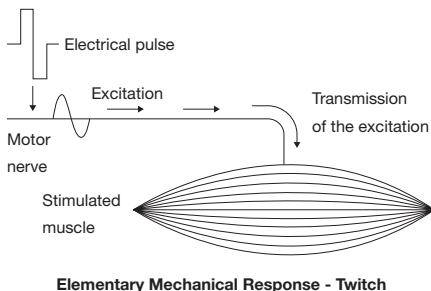
How Does Electrostimulation Work?

The principle of electrostimulation is to stimulate nerve fibers by means of electrical impulses transmitted by electrodes. The electrical pulses generated by Empi Elite stimulators are high quality pulses - offering safety, comfort and efficiency - which stimulate motor points of the target muscle resulting in a muscle contraction. The benefits obtained depend on the stimulation parameters and this is known as electro-muscular stimulation (EMS).

Motor nerve stimulation (EMS)

In voluntary activity, the order for muscular work comes from the brain, which sends a command to the nerve fibers in the form of an electrical signal. This signal is then transmitted to the muscular fibers, which contract. The principle of electrostimulation accurately reproduces the process observed during a voluntary contraction. The stimulator sends an electrical current impulse to the nerve fibers, exciting them. This excitation is then transmitted to the muscular fibers causing a basic mechanical response (= muscular twitch). The latter constitutes the basic requirement for muscular contraction. This muscular response is completely identical to muscular work controlled by the brain. In other words, the muscle cannot distinguish whether the command comes from the brain or from the stimulator. The parameters of the Empi Elite programs (number of impulses per second, contraction time, rest time, total program time) subject the muscles to different types of work, according to muscular fibers. In fact, different types of muscular fibers may be distinguished according to their respective contraction speed: slow, intermediate and fast fibers. Fast fibers will obviously predominate in a sprinter, while a marathon runner will have more slow fibers. With a good knowledge of human physiology and a perfect mastery

of the stimulation parameters of the various programs, muscular work can be directed very precisely towards the desired goal (muscular reeducation, relaxation of muscle spasm, increased blood flow, maintaining or increasing range-of-motion, etc.).



Benefits of electrostimulation

Electrostimulation is a very effective way to make your muscles work.

- with significant improvement of different muscular qualities
- without cardio-vascular or mental fatigue
- with limited stress on the joints and tendons. Electrostimulation thus allows a greater quantity of work by the muscles compared with voluntary activity.

To be effective, this work must involve the greatest possible number of muscular fibers. The number of fibers working depends on the stimulation energy. The maximum tolerable energy should therefore be used. The user controls this aspect of stimulation. The higher the stimulation energy, the greater the number of muscular fibers that are working and, therefore, the more significant the progress achieved.

Explanation of Symbols

The following symbols are used either in this user manual, on the device packaging, or on the device label. They may also appear on an accessory.



Consult the instructions for use.



Follow instruction for use.



Type BF applied parts.



Keep the device dry.



Keep the device away from sunlight.



Do not wear electrode or controller during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and causing skin burns in the area of the patch.



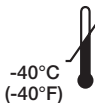
For prescription only.



ETL Classified US, 9900900, Electronic Testing Lab, indicates product meets US safety standards. This device complies with UL STD 6060101.



Council Directive 2002/96/EC concerning Waste Electrical and Electronic Equipment (WEEE). Indicates a requirement not to dispose of WEEE as municipal waste. Contact your local distributor for information regarding disposal of the unit and accessories.



70°C (158°F) TRANSPORT & STORAGE



Date of Manufacture.



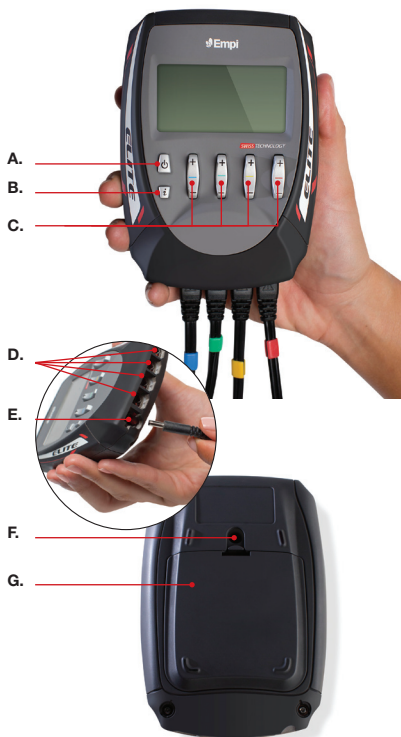
Reference number; part number. Lead wires comply with the Performance Standard for electrode lead wires (21 CFR part 898).

Operating Instructions

You are strongly advised to carefully read Warnings and Cautions section (pages 3-6) described at the beginning of this manual prior to using your stimulator.

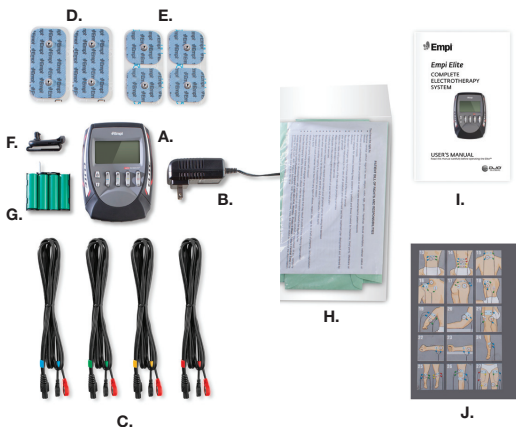
Description of the stimulator

- A. On/Off button
- B. “I” button used to: increase stimulation energies in several channels simultaneously
- C. (1, 2, 3, 4) +/- buttons for each of the 4 stimulation channels
- D. Sockets for the 4 leadwires
 - Channel 1 = blue
 - Channel 2 = green
 - Channel 3 = yellow
 - Channel 4 = red
- E. Socket for the battery charger (Disconnect all leadwires before inserting the charger pin)
- F. Belt clip socket
- G. Rechargeable battery compartment



Your kit contains

- A. 1 stimulator
- B. 1 charger
- C. 1 set black snap connectors (lead wires) for electrodes, color coded (blue, green, yellow, red)
- D. 2 bags of large snap electrodes 2x4 in (5x10cm)
- E. 2 bags of small snap electrodes 2x2 in (5x5cm)
- F. 1 belt clip
- G. Rechargeable battery pack
- H. 1 patient information packet
- I. 1 user manual
- J. 1 electrode placement guide



Connections

1. Connecting the cables

The stimulator cables plug into the 4 sockets on the front bottom of the device. Four lead wires can be connected simultaneously to the four channels of the device. Both the sockets and the lead wires are color-coded to simplify use and facilitate identification of the different channels.

blue = channel 1

green = channel 2

yellow = channel 3

red = channel 4

2. Connecting the electrodes

Each lead wire has a red snap (positive lead) and a black snap (negative lead). Connect the lead by snapping the lead on the electrode. Once you snap on the lead, the lead should stay directly on the electrode. **Note:** use the electrode placement pictures to correctly position the positive and negative leads.

3. Electrode placement

Please refer to the following pictogram for the electrode placements. Install yourself comfortably in the position shown on the pictogram.

Always follow your doctor's recommendations for the electrode placement and for the intensities applied.

This section is located at the end of this manual.

4. Connecting the charger

Empi Elite has rechargeable batteries and can be recharged.

Remove any leadwires connected to the stimulator before recharging it. To recharge them, use the charger supplied with your device and connect it to the front of the device, then plug the charger in a socket.

Never try to plug leadwires simultaneously with the charger. We strongly recommend you fully charge the battery before using it for the first time as this will improve its life span.

Preliminary settings

Before using the unit for the first time, you should select the working language of the device which is displayed on the options screen. Follow the instructions below. Afterwards, for the greatest comfort, the Empi Elite offers you a number of setting options (operating language selection, display contrast setting, adjusting backlighting and volume setting). To change any of these settings, bring up the options screen by holding the On/Off button on the left of the stimulator for a few seconds when the device is being turned on.



A: Press the On/Off button to turn on your stimulator or to bring up the option screen. It is now ready for use with the settings you selected.

B: Use the channel (C1) +/- button to choose the language you wish to use.

Use the channel (C2) +/- button to adjust the contrast of the screen.

Use the channel (C3) +/- button to adjust the volume.

Use the channel (C4) +/- button to adjust the backlighting.

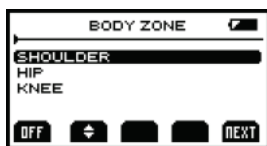
On: backlighting always on.

Off: backlighting always off.

Auto: backlighting activated whenever a button is pressed.

Selecting a body area

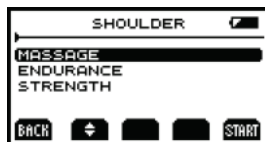
This menu allows the patient to select which body area she/he would like to treat. There are 3 different possible body areas selectable: SHOULDER, HIP and KNEE.



- Press the On/Off (A) button to go to the previous screen.
- Use the channel (C1) +/- button to choose a body area.
- Press the channel (C4) +/- button to validate your selection and go to the treatment selection menu. The corresponding symbol on the display is a black case with 'NEXT' written in it.

Selecting a treatment

To choose a treatment, consult your medical professional. It is also particularly useful to consult chapter VI "Programs".



- Press the On/Off (A) button to go to the previous screen.
- Use the channel (C1) +/- button to choose treatment program.
- Press the channel (C4) +/- button to validate your selection and go to the treatment selection menu. The corresponding symbol on the display is a black case with 'START' written in it.

During the stimulation session

1. Adjusting stimulation energies

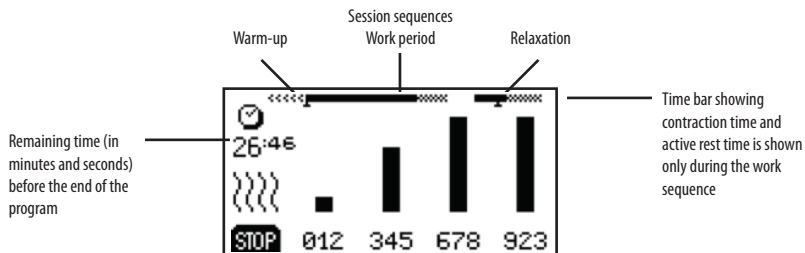
When you start a treatment, you will be prompted to increase the stimulation energies. This is critical to the success of any program. The energy level should be based on the guidance of your prescribing practitioner.



- Press the On/Off (A) button to place the unit in Pause mode.
- The Empi Elite "beeps" and the symbols of the four channels flash, the four channels are at 000 energy. You must increase the stimulation energy so that the stimulation can start. To do this, press the + buttons (C1, C2, C3, or C4) for the relevant channels until the desired setting is reached. If you want to increase the energy level of all four channels simultaneously, press the "i" button (B), located below the On/Off button (A). Press the "i" button twice to increase the levels in the first 3 channels, and 3 times to increase the levels in the First 2 channels. When you press the "i" button, the associated channels are overlighented in black.

2. Program progression

Stimulation actually starts when the stimulation energy has been increased. The examples reproduced below show the general rules.



- The different energies reached during the contraction phase are shown by a series of black bar graphs.
- Active rest phase energies are shown by checkered bar graphs.
- Active rest phase stimulation energies are automatically set at 50% of contraction energies. These can be modified during the rest phase. Once modified, they will be totally independent of the contraction energies.

3. Program pause mode

- Press the On/Off button (A) to interrupt the program momentarily. To restart, simply press the channel 4 (C4) +/- button. The session will resume at 80% of the energy levels that were in use prior to the interruption.

- Use the channel 4 (C4) +/- button to resume the program at the chosen sequence.

NOTE: The skip function is not available for all programs. It should also be noted that this function can reduce the effectiveness of a program if used to shorten the work sequence excessively.

4. Skip function (Endurance & Strength program only)

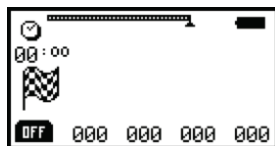
The skip function allows you to end the current program phase and move on to the next one. For skip function to work, the unit must be in Pause mode.



- Press the On/Off button (A) to return to the previous list of programs
- Use the channel 3 (C3) +/- button to skip a particular sequence of a program. When you do this, the unit will beep and the cursor will move to the beginning of the next sequence.

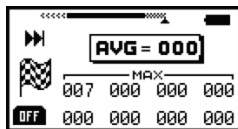
5. End of program

At the end of each session, a small flag will be displayed on the screen and a short melody will be played. To switch off the stimulator, press the On/Off button (A).



For the ENDURANCE and STRENGTH programs (when a muscle work has been performed), the end session screen will also provide the average value (AVG) of the stimulation level and the maximum (MAX) level reached for each channels. The skip

icon will also be monitored if the program has been completed by using the skip function.



Consumption and recharging

Never recharge the stimulator without first disconnecting the leadwires. Always use the charger supplied by Empi to recharge the batteries.

The Empi Elite runs on rechargeable batteries. The battery's life depends on the programs and stimulation energy used. We strongly recommend you fully charge the battery before using your Empi Elite for the first time as this will improve the length of usable time and life span. If you do not use your device for a long period of time, please recharge the battery regularly.

1. Charge level

The charge state of the battery is indicated by a small battery icon on the screen.

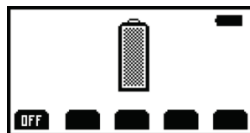


If the battery icon is only 1/3 blackened, this means that power is running low. At this stage the device should be recharged. Don't start a new program when the battery level is below 1/3 as it may not be possible to complete a program.

If the symbol normally displayed above the channel 4 +/- button (C4) is not visible and if the battery icon is flashing, this means that the battery is completely discharged. It is no longer possible to use the device. Recharge it immediately.

2. Recharging

Remove all leadwires from the stimulator before recharging the battery. To recharge it, use the charger supplied with your device and connect it to the front of the device, then plug the charger cable in the charging socket (E) and then plug the charger to an electrical outlet. The charge menu shown below will automatically appear on the screen.



The duration of the charging operation is shown on the screen (a complete charge may take 10 hours).

The battery icon is animated while the battery is recharging. When fully charged, the icon will be full and the total time taken to recharge the battery will flash on the screen. Simply disconnect the charger. Empi Elite will turn off automatically.

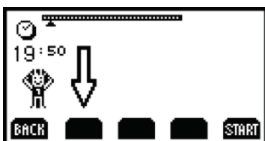
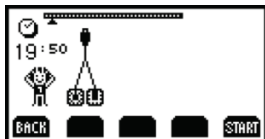


Plugging the charger cable into the charging socket.

Problems and solutions

1. Open lead detection

The Empi Elite “beeps” and alternatively displays the symbol of a pair of electrodes and an arrow pointing to the channel where a problem has been detected. In the example below, the stimulator has detected an error in channel 1.



- Check whether the lead wire is plugged into this channel completely.
- Check whether electrodes are connected to each lead.
- Check whether electrodes are placed on your body correctly.
- Check whether the electrodes are old, worn, and/or the contact is poor: try using new electrodes.
- Try using the stimulation cable on a different channel. If the cable is still showing a fault, replace it.

2. Stimulation is not producing the usual sensation

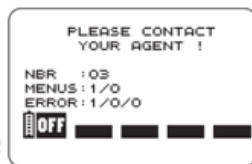
- Check that all the settings are correct and ensure the electrodes are positioned properly.
- Change the positioning of the electrodes slightly.

3. The stimulation effect causes discomfort

- The electrodes are beginning to lose adhesion and no longer provide good contact on the skin.
- The electrodes are worn and need to be replaced.
- Change the positioning of the electrodes slightly.

4. The stimulator is not working

If an error screen appears while you are using the device, write down the menu code and error number (in the example below, menu code 1/0 and error number 1/0/0) and contact the nearest authorized customer support service or Elite Product Support.



Product Support

Toll free: 800-862-2343

Empi, Inc.
205 Hwy 22 East
Clear Lake, SD 57226 USA

Programs

The Empi Elite provides three muscle stimulation training programs which correspond to target muscle groups (Shoulder, Knee, Hip) of the patient intended for use during rehabilitation. These rehabilitation programs are:

- Massage
- Endurance
- Strength

You must consult your medical professional for the proper protocol to follow.

Massage

The Empi Elite Massage program is intended to relax muscle spasms, reduce the muscular spasticity, and enable the target muscles to contract effectively.

This program is recommended for use as needed before and after surgery as prescribed by your medical professionals.

MASSAGE (21 minutes)			
Reference name used in Europe: Relaxing			
	1st sequence	2nd sequence	3rd sequence
Frequency	7 [Hz]	5 [Hz]	3 [Hz]
Time	7 min	7 min	7 min
Pulse width: Shoulder	250 [us]		
Hip	300 [us]		
Knee	380 [us]		

Endurance

The Empi Elite Endurance program focuses on activating an average medium working level on muscle fibers. This working level is maintained over an extended period of time (25 minutes per session). The Endurance program particularly activates the aerobic metabolism of the fibers during the stimulation session. The purpose is to increase the time for the muscle to maintain a medium level of working power or the average power level for extended periods of time.

ENDURANCE (25 minutes)				
Reference name used in Europe: Disuse atrophy level1				
	Warm-up	Contraction	Active rest	Final recovery phase
		74 cycles		
Frequency	6 [Hz]	35 [Hz]	4 [Hz]	3 [Hz]
Duration of ramp-up	1.5 s	1.5 s	0.5 s	1.5 s
Duration of phase	2 min	6 s	7 s	3 min
Duration of ramp-down	2 s	0.75 s	0.5 s	3 s
Pulse width: Shoulder 2	50 [us]			
Hip	300 [us]			
Knee	380 [us]			

Strength

The Empi Elite Strength program imposes a high and instantaneous power working level on muscle fibers. These contractions are separated by long periods of rest. The result is an average medium power working level (+ 20 minutes). This program is intended to increase the maximum strength of muscle isometric contraction. This program targets the muscle fibers that are typically afflicted with immediate atrophy after injury or/and surgery.

This program is recommended for use only after having completed at least 10 sessions of the previous Endurance program as prescribed by your medical professionals.

STRENGTH (20 minutes)				
Reference name used in Europe: Reinforcement level1				
	Warm-up	Contraction	Active rest	Final recovery phase
		52 cycles		
Frequency	6 [Hz]	75 [Hz]	4 [Hz]	3 [Hz]
Duration of ramp-up	1.5 s	1.5 s	0.5 s	1.5 s
Duration of phase	2 min	4 s	10 s	3 min
Duration of ramp-down	2 s	0.75 s	0.5 s	3 s
Pulse width: Shoulder	250 [us]			
Hip	300 [us]			
Knee	380 [us]			

Practical Information

Maintenance

Do not sterilize the stimulator. Clean using a soft cloth and an alcohol based, solvent-free cleaning product. Use only a minimum amount of liquid when cleaning the Empi Elite.

Do not attempt to repair the stimulator or any of its accessories. Never dismantle the Empi Elite or the charger containing high-voltage parts because of risk of electric shock. Empi declines all responsibilities for any damages or consequences resulting from unauthorized attempts to open, modify, or repair the stimulator. This may only be done by persons or repair services authorized by Empi.

Your stimulator does not require calibration. Each Empi Elite stimulator is always tested and validated prior to distribution. Its characteristics do not vary under normal conditions. Nonetheless, as the Empi Elite is a high quality electrical instrument, its lifespan depends on the use that is made of it and the care and maintenance it receives

during its lifetime. If your stimulator contains parts that seem worn or defective, please contact your nearest Empi customer service center regarding a replacement unit.

Storage and transportation conditions

The Empi Elite contains rechargeable batteries. This is why it must be stored and transported in accordance with the following conditions:

- Storage and transportation temperature: from -20°C (-4°F) to 45°C (113 °F)
- Maximum relative humidity: 75%
- Atmospheric pressure: 700 hPa to 1060 hPa
- Conditions of use
- Temperature: 0°C (32°F) to 40°C (104°F)
- Relative humidity: 30% to 75%
- Atmospheric pressure: 700 hPa to 1060 hPa
- Do not use in areas where there is a risk of explosion.

Disposal

To prevent the creation of waste electrical and electronic equipment (WEEE) and to reduce the amount of waste to be disposed, we encourage reuse, recycle and other forms of recovery. The wheelie bin pictogram with the bar through it means that the equipment cannot be discarded with household refuse, but that it must be collected selectively. The equipment must be delivered to a suitable collection point for treatment. By doing so, you will be contributing to the safeguarding natural resources and health. Batteries must be disposed of in compliance with relevant national or state regulatory requirements.

Standards

The Empi Elite complies with current medical standards.

To guarantee your safety, the Empi Elite has been designed, manufactured, and distributed in compliance with the requirements of IEC 60601-1 standard on general safety requirements for electro-medical devices, IEC 60601-1-2 standard on electromagnetic compatibility, and the IEC 60601-2-10 standard on particular safety requirements for nerve and muscle stimulators.

Patents

The Empi Elite incorporates several innovations with patents pending. Normalized symbols

Technical characteristics

- Device connector: 6-pin
- Electrode connector: female Snap
- Length: 1500 mm
- Protection index
- Protection: IPX0 Neuro-stimulation
- All electrical specifications are given for an impedance of 500-1000 ohms per channel.
- Channels: Four independent and individually adjustable channels that are electrically isolated from each other and earthed.
- Pulse shape: Constant rectangular current with pulse compensation to eliminate any direct current component to prevent residual polarization at skin level.
- Maximum pulse intensity: 120 mA.
- Pulse intensity increments: manual adjustment of stimulation intensity from 0 to 999 (energy) in minimum increments of 0.5 mA.
- Pulse width: 200 to 380 μ s.
- Maximum electrical charge per pulse: 96 microcoulombs (2x48 μ C, compensated).
- Standard pulse ramp-up time: 3 μ s (20%-80% of maximum current).
- Pulse frequency: 1 to 120 Hz.

EMC Table (Electromagnetic Compatibility)

The Empi Elite needs special EMC precautions and must be installed and started according to the EMC information supplied in this manual.

All RF wireless transmission systems could affect the Empi Elite. The use of accessories, other than those recommended by the manufacturer may result in stronger

emissions or reduce the immunity of the Empi Elite.

The Empi Elite should not be used beside or stacked on top of any other equipment. If you must use it side by side or on top of another system, you should check that the Empi Elite works properly in the chosen configuration.

Specifications

TABLE 1: RECOMMENDATIONS AND DECLARATION BY THE MANUFACTURER CONCERNING ELECTROMAGNETIC EMISSIONS


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

Emission Tests	Compliance	Electromagnetic Environment - Guidance
CISPR 11 RF Emissions	Group 1	The Empi Elite uses RF energy only for its internal operation. Consequently, its RF emissions are very low and are unlikely to interfere with any adjacent electrical device.
CISPR 11 RF Emissions	Class B	The Empi Elite is suitable for use in any establishment, including a private dwelling and a place connected directly to the low voltage mains supply which powers residential buildings.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Emission Oscillations IEC 61000-3-3	Not Applicable	

TABLES 2 & 3: RECOMMENDATIONS AND DECLARATION BY THE MANUFACTURER - ELECTROMAGNETIC IMMUNITY

The Empi Elite is designed for use in the electromagnetic environment stipulated below. The customer or the user of the Empi Elite must ensure that it is used in this recommended environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV at the contact ±8 kV in air	±6 kV at the contact ±8 kV in air	Floors must be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at a minimum of 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable System battery-powered	The quality of the power supply should be that of a typical commercial or hospital environment.
Surge (1) IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable System battery-powered	The quality of the power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not Applicable System battery-powered	The quality of the power supply should be that of a typical commercial or hospital environment. If the Empi Elite user requires continuous operation during mains power cuts, we recommend that the Empi Elite is powered by a UPS or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m		Magnetic fields at the mains frequency should be at the level of a representative site located in a typical commercial or hospital environment.
			Portable and mobile RF communications equipment should be used no closer to any part of the Empi Elite, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

			Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 10 V/m 26 MHz to 1 GHz	3 V/m 10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			<p>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 meters (m).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. A 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 Empi Elite are used exceeds the applicable RF compliance level above, the Empi Elite should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Empi Elite. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**TABLE 4: RECOMMENDED SPACING BETWEEN A
PORTABLE AND MOBILE COMMUNICATION APPLIANCE
AND THE EMPI ELITE**

The Empi Elite is designed for use in an electromagnetic environment in which radiated RF waves are controlled. The buyer or user of the Empi Elite can contribute to preventing electromagnetic interference by maintaining a minimum distance between RF portable and mobile communication appliances (transmitters) and the Empi Elite according to the table of recommendations below and according to the maximum output power of the telecommunication appliance.

Maximum Transmitter Output Power	Spacing according to the frequency of the transmitter m CISPR 11		
	From 150 kHz to 80 MHz $d = 1.2\sqrt{P}$	From 80 MHz to 800 MHz $d = 1.2\sqrt{P}$	From 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

In the case of whose maximum output power is not shown in the table above, the recommended spacing of d meters (m) can be calculated using the appropriate equation for the transmitter frequency, where P is the maximum output power of the transmitter in watts (W) as set by the transmitter manufacturer.

NOTE 1: At 80 MHz and at 800 MHz, the spacing for high frequency amplitude is applied.

NOTE 2: These guidelines may not be appropriate for some situations. Electromagnetic wave propagation is modified by absorption and reflection due to buildings, objects, and persons.

Limited Warranty

Warning

While, in the opinion of Empi, Inc. the use of the Empi Elite (“the Product”) has met with some success, Empi, Inc. makes no warranties to the purchaser as to the effectiveness of the product.

Warranty

- A. Empi, Inc. warrants to the initial Purchaser (“Purchaser”) (and to no other person) that the Product (with the exclusion of accessories such as chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream) and the component parts thereof, distributed or manufactured by Empi, Inc., shall be free from defects in the workmanship and materials for three years from the initial date of purchase from Empi, Inc. (the “Warranty Period”).
- B. Accessories including, but not limited to, chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream are excluded from the Warranty and sold “AS IS” because their structure is such that they may be easily damaged before or during use.

Limitation of Liabilities and Disclaimer or Warranties

- A. Empi, Inc.’s sole obligation in the case of any breach of its warranties set forth in Paragraph A in the Warranty section above, shall be, at Empi, Inc.’s option, to repair or replace the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Empi, Inc. written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period and within 30 days of discovery of the defect. Upon Empi, Inc.’s written request and authorization, Purchaser shall return the Product to Empi, Inc., freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to Empi, Inc. at 47492 Hwy. 22, Clear Lake, South Dakota 57226, USA, or to an Empi, Inc. Authorized Service Center. To locate the appropriate Service Center outside of North America, or to request shipment approval, contact Empi, Inc. directly. Empi, Inc. will not be responsible for damage due to improper packaging or shipment. If Empi, Inc. determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Empi, Inc. will refund to the Purchaser, the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, the purchase price for the defective product, or return the insurance prepaid, as soon as reasonably possible following receipt of the Product by Empi, Inc.. Empi, Inc. determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Empi, Inc. will return the Product to the Purchaser, freight and insurance billed to the Purchaser.
- B. This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Empi, Inc. or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

- C.** Except as provided in paragraph A, the product is being sold on an as is basis, all accessories are sold as is, and the entire risk as to the quality and performance of the product is with purchaser. The warranty provided in paragraph A is intended solely for the benefit of the initial purchaser and Empi, Inc. disclaims all other warranties, express or implied including, but not limited to, any implied warranties of merchantability and fitness for a particular purpose; provided, however, that notwithstanding the foregoing sentence, in the event an implied warranty is determined to exist, the period for performance by Empi, Inc. thereunder shall be limited to the lifetime of the initial purchaser. No employee, representative or agent of Empi, Inc. has any authority to bind Empi, Inc. to any affirmation, representation or warranty except as stated in this written warranty policy.
- D.** Empi, Inc. shall not be liable to any person for any direct, indirect, special, incidental or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against Empi, Inc. (e.g. contract, negligence or otherwise) the remedy provided in paragraph A above shall constitute purchaser's sole remedy. In no event shall Empi, Inc.'s liability under any cause of action relating to the product exceed the purchase price of the product. This Warranty gives the purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.

Ordering Information

To reorder call: Empi at 800.328.2536

Part	Product Number
Empi Elite Stimulator	199729
Small Snap Electrodes 2x2 in (5x5 cm)	199725
Large Snap Electrodes 2x4 in (5x10 cm)	199730
Battery Charger	683026
Snap Connectors (lead wires)	601131
Rechargeable Battery Pack	941213 or 941210
Belt Clip	949000



199730



199725

949000



941213



199729



683026



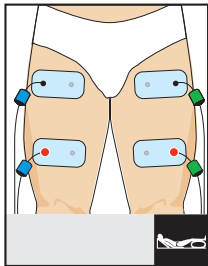
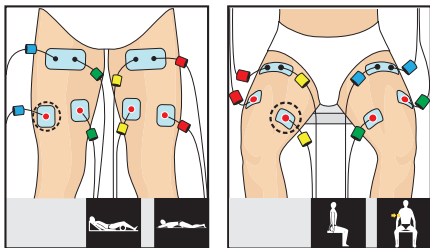
601131

Electrode Placement Examples

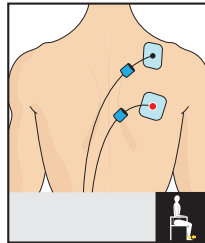
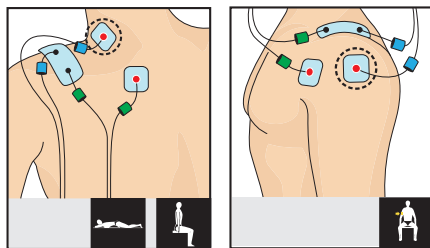
Please refer to the following pictogram for electrode placement. Install yourself comfortably in the position shown in the pictogram.

Always follow your doctor's recommendations for the electrode placement and for the intensities applied.

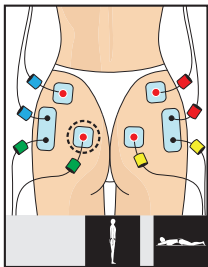
For **Knee** treatment, typical electrode placements are:



For **Shoulder** treatment typical electrode placements are:



For **Hip** treatment, typical electrode placements are:



Made in Tunisia for Empi



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205 Hwy 22 East
Clear Lake, SD 57226 USA
651.415.9000; 800.328.2536

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