

"jožef stefan" institute, ljubljana, slovenia

STIMULATOR ALT-2

INSTRUCTIONS FOR USE

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Instructions for use of the Alternating Dual Channel Stimulator ALT-2

1. Description

The ALT-2 stimulator is a high current output functional electrical stimulation (FES) device designed for strengthening of the atrophied paralysed muscles, and for standing up from the sitting position, standing, and gait in spinal cord injury (SCI) patients. The stimulator can be used as an adjunct in therapy program or as an orthotic aid for everyday use in home environment.



Figure 1: ALT-2 stimulator set with water-soaked electrodes, electrode cable and manual switch.

For standing and gait of a complete paraplegic person a set with two ALT-2 stimulators is required. Stimulator ALT-2 may also be used for the strengthening of muscles and correction of gait in paraparetic and tetraparetic persons. In such patients, one lower extremity is often considerably weaker compared to the other, so one stimulator may be sufficient to achieve the required function. The stimulator can be further applied in learning of movements after longer periods of immobilisation of the extremity, in atrophy due to inactivity and in postoperative conditions. It may be convenient for extreme muscle training in athletes.

ALT-2 stimulator is provided in three different kits (content of kit may vary in different countries):

ALT-2 Model 2000 Professional Kit, consisting of:

- 2 ALT-2 stimulators
- 4 sets of water soaked electrodes or 3 packages of self-adhesive electrodes
- 4 manual control switches
- 4 electrode connective cables
- 6 elastic Velcro straps (only with water soaked electrodes)
- 4 rechargeable batteries
- 1 battery charger
- 1 storage case
- 1 operations manual

ALT-2 Model 1000 Personal Kit, consisting of:

- 2 ALT-2 stimulators
- 4 sets of water soaked electrodes or 3 packages of self-adhesive electrodes
- 4 manual control switches
- 4 electrode connective cables
- 6 elastic Velcro straps (only with water soaked electrodes)
- 4 rechargeable batteries
- 1 battery charger
- 1 operations manual

ALT-2 Model 500 Personal Kit, consisting of:

- 1 ALT-2 stimulator
- 2 sets of water soaked electrodes or 2 packages of self-adhesive electrodes
- 2 manual control switches
- 2 electrode connective cables
- 3 elastic Velcro straps (only with water soaked electrodes)
- 2 rechargeable batteries
- 1 battery charger
- 1 operations manual

1.1 Purpose of Use

Atrophy of skeletal muscle occurs whenever muscle is denervated, that is, when the motor axons to muscle degenerate. Atrophy will also occur when central nervous system (CNS) is no longer capable of activating motoneurons, as occurs following CNS injury (e.g. spinal cord injury). As opposed to the absolute denervation associated with peripheral nerve injury, the functional denervation of CNS disorders results in muscle atrophy and strength loss that may be managed using the ALT-2 stimulator. In complete lesions FES is the only method that enables us to activate paralysed muscles and thus prevent their atrophy and other symptoms associated with muscle disuse (e.g. contractures, osteoporosis, blood circulation problems). Such muscle contraction, when strong enough, can be used for eliciting functional movement or for supporting the body weight. By incorporating this principle with the

ALT-2 stimulator, an active and relatively easy verticalisation or even simple gait can be achieved in complete SCI patients.

In orthopaedic patients a disuse atrophy of muscles appears after prolonged limb or joint immobilisation. After surgical treatment (e.g. total hip replacement, osteosynthesis) partial peripheral nerve lesions occur. In such cases FES is a most convenient tool that enables the patient to improve contraction force and increase endurance of the affected muscle. FES is also convenient for muscle strengthening when little or no load to the bone is allowed.

1.2 Indications

The application of ALT-2 stimulator is indicated for patients with incomplete and complete spinal cord injuries and consequential spastic paresis. Due to the nature of injury and consequential surgical procedures partial or complete peripheral denervation of certain muscles may occur. Partial denervation of stimulated muscles is acceptable for application of ALT-2 stimulator for standing or gait when required muscle torque may be generated by the stimulated muscle. In complete SCI patients generally those with lesion between level C6 and Th10 are candidates for standing and gait program. This limits, however, are only a guideline. Each patient should be thoroughly assessed before commencing the program.

Typical Indications:

- patients with unilateral or bilateral spastic paralysis of lower extremities with intact peripheral motoneurons
- patients with unilateral or bilateral paralysis combined with partial muscle denervation
- orthopaedic rehabilitation patients after musculo-skeletal trauma or surgery, who suffer from weak or atrophied muscles due to inactivity.

IMPORTANT! Preserved excitability of motor nerve fibres, neuromuscular transmission (at least partially) and contractability of the stimulated muscles is required.

The following conditions are required for the application of ALT-2 stimulator:

- satisfactory physical state of the patient
- compensated cardiovascular system
- intact skin on the site of stimulation
- preserved contractile properties of stimulated muscles
- absence of strong spasticity
- absence of contractures or other deformities of the locomotor apparatus
- motivation and collaboration of the patient

For the orthotic use there is also required:

- satisfactory electrical excitability of the peripheral nerves and muscles
- mobility of the patient without or with aids (crutches, support by another person, etc.)
- adequate eyesight

- ability of the patient to handle, control the operation and maintain the stimulator by himself/herself.

Special considerations:

- osteoporosis
- severely limited muscle endurance
- severe spasticity
- pre-existing conditions such as heart disease or epilepsy

2 Instructions for the Patient

2.1 Preparation of Electrodes

2.1.1 Water-soaked Electrodes

Wet the electrodes with ordinary tap water before using the stimulator. Distilled or atmospheric water should not be used. New or very dry electrodes should be soaked in water for a while.

2.1.2 Self-adhesive Electrodes

Follow the instructions for use on the electrode bag.

2.2 Positioning the Electrodes and the Stimulator

Adequate size electrodes should be positioned on the sites determined by the physiotherapist. Self-adhesive electrodes should be pressed firmly to the skin. No fixation is required. In case of water soaked electrodes, they should be attached using the elastic Velcro straps. The stimulator is attached conveniently to one of the elastic Velcro straps using the clip on the back side of the stimulator. The electrode cable is connected to the stimulator at the side, while both intensity knobs are set to “OFF”. The position of the socket is denoted by the symbol **ELECTRODE** on the housing of the stimulator. The electrode connectors of the electrode cable are attached to electrodes.

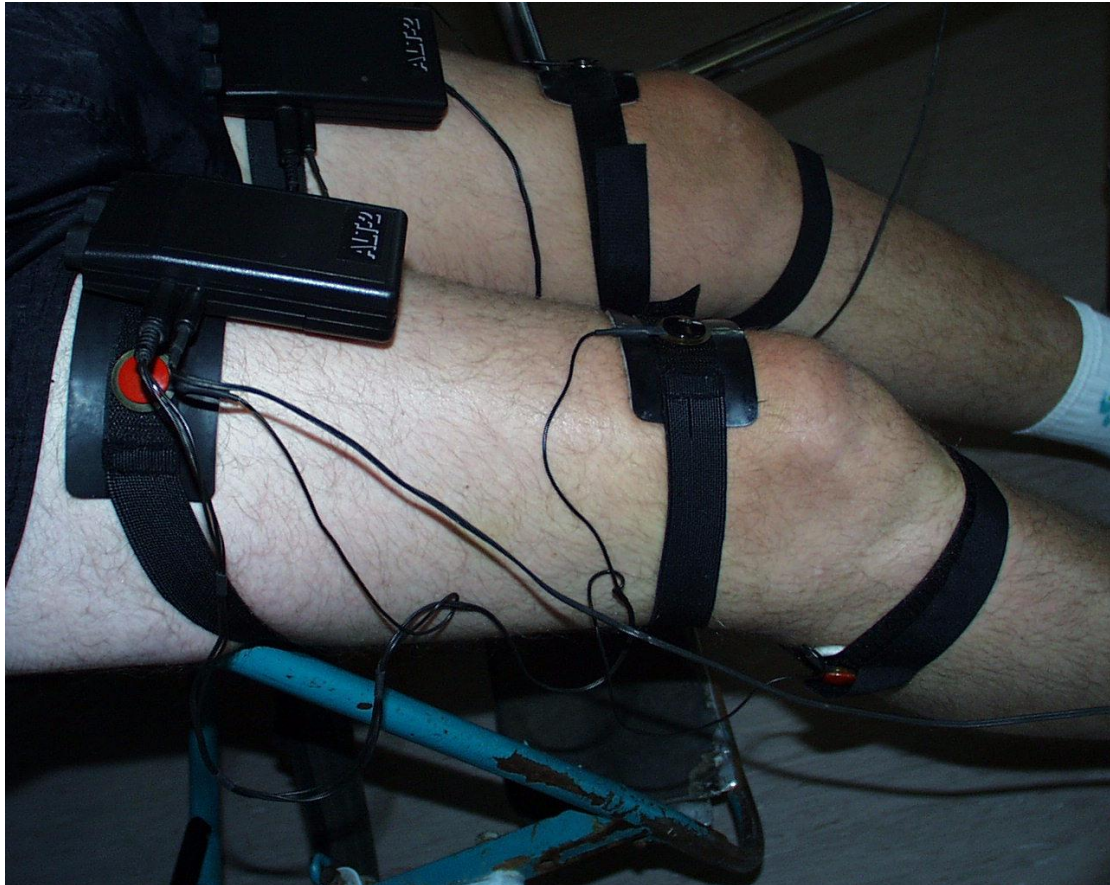


Figure 2: Position of electrodes along the knee-extensor muscles and on peroneal nerve.

2.3 Control of the Stimulation Intensity

The ALT-2 stimulator is turned on when either of intensity knobs is turned clock-wise from “OFF” position to “ON” position or further more. The numerical settings denote parts of the full scale (180mA) and not stimulation current amplitude. Increasing the number proportionally increases the intensity of stimulation. The line over the yellow indicator beside the intensity knob indicate the position of the knob. The light intensity of the indicator varies proportionally to the stimulating current through electrodes.



Figure 3: ALT-2 stimulator showing the position of stimulation intensity knobs and sockets for electrode connector (ELECTRODE) and manual control switch (SWITCH) connector.

The adequate stimulation intensity should be determined according to the following procedure. When stimulator turned off, the electrode cable should be connected to the electrodes and to the stimulator. The manual switch is disconnected. After the stimulator is turned on the manual switch is connected and the push-button is released. This provides continuous stimulation on channel 1. By gradual increasing the intensity (turning channel 1 knob clockwise) the muscle contraction is observed. When adequate contraction is achieved, the position of the knob is memorised and the intensity is reduced to 0. The channel 2 intensity is set by following the same procedure as described for channel 1 except that in this case the manual switch is depressed all the time, thus providing constant stimulation on channel 2.

Warning! ALT-2 stimulator is high output current device, therefore, one must be extremely careful while increasing the intensity in patients with intact sensation.

2.3.1 Waveform

The ALT-2 stimulator generates constant current, rectangular, balanced, asymmetrical, biphasic stimulating pulses. Fig. 4 shows waveforms of three stimulating pulses of different intensity, recorded on 1.5 k Ω load resistor. The mean positive pulse intensities are 50 mA, 100 mA and 180 mA respectively. The maximum R.M.S. values of stimulating pulses are 9.9 V and 8 mA respectively.

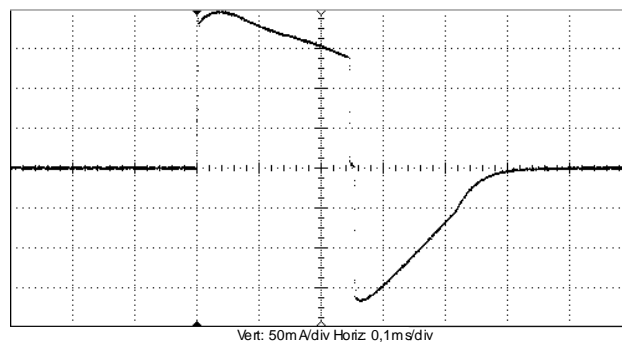
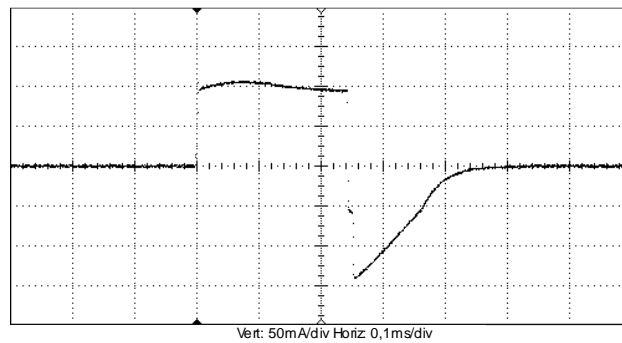
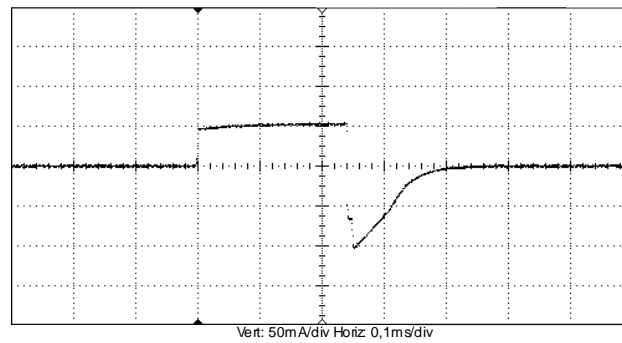


Figure 4: The waveforms of stimulating current at three different intensities (50 mA, 100 mA and 180 mA).

2.4 Operating Modes

ALT-2 has two modes of operation: intermittent and manually controlled. The intermittent mode of operation is selected when no manual switch is connected to the stimulator. In such case there will be 4 seconds on and 4 seconds off intermittent stimulation alternating between the channels. This mode is used for muscle strengthening program.

The manual controlled mode is selected when the manual push-button switch is connected to the stimulator. The symbol **SWITCH** on the housing of the stimulator shows the position of the socket, where the connector of the manual push-button

switch is to be plugged in. If the manual push-button switch is connected to the stimulator when the stimulator is already turned on, the intermittent mode is suspended and manual mode is invoked. When the manual push-button switch is released the stimulation is constantly present on channel 1 and there is no stimulation on channel 2. While the manual switch is depressed the stimulation is constantly present on channel 2 and there is no stimulation on channel 1. This mode enables the patient or the therapist to manually control the operation of the stimulator (e.g. in gait).

To enable easier standing up manoeuvre an additional feature - so called “click” function, has been implemented in ALT-2 stimulator. When the stimulator is turned on with manual switch already connected, there will be no output on either stimulation channel. This enables the patient to set the pre-defined stimulation intensities on both channels without actually eliciting the muscle contraction. Thus, one may position himself/herself into the most convenient position for standing up. When ready, a click on the push-button (actually the action of releasing the manual switch) will trigger the stimulation on channel 1. Afterwards the manual control and the stimulator function the same way as described above.

2.5 Safety Precautions

- The ALT-2 stimulator is designed to be used with specific electrodes. If other types of electrodes or too dry electrodes are used, a potential hazard of skin burns may exist. In such a case, discontinue the stimulation and consult your therapist.
- The unit must be turned off prior to attaching or detaching the electrodes. Increase the intensity gradually.
- Do not apply the electrodes over an open wound, cut or other skin lesion
- Never place the electrodes on thorax or neck.
- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation in close proximity (e.g. 1m) to a short-wave or microwave therapy equipment may produce instability in the stimulator output.
- Keep the device out of reach of children.
- Do not operate potentially dangerous machinery or drive the car during use of the stimulator.
- Never use or operate the stimulator in the presence of explosive atmosphere.

2.6 Maintenance of the Stimulator

The stimulator case could be cleaned with a damp cloth and a mild soap water solution. Do not submerge the device in water as it will adversely affect the electronic components.

Every now and then clean the water soaked electrodes (without the cable) with a mild soap and water. When they get uncleanably dirty or damaged, replace them. With daily use they should last approx. two months. After use always dry the water soaked electrodes.

Self-adhesive electrodes should be taken care of according to the instructions presented by the producer on the electrode container.

Warranty does not apply to batteries, cables, heel-switches and electrodes which wear out due to everyday use.

When properly maintained the life time of the Alt-2 stimulator is 7 years.

2.7 Procedure to check normal operation of the ALT-2 stimulator

To different procedures are available to check the operation of the ALT-2 stimulator:

- quick check, based on observing the light indicators and muscle contraction, which can be performed by the patient or physiotherapist
- technical check, which can be performed by a electrotechnician and requires some additional measuring equipment.

2.7.1 Quick Check

Quick check may be performed by applying the electrodes to the usual position, attaching the stimulator and electrode leads without connecting the manual-switch. The stimulator should operate in intermittent mode - 4 seconds stimulation on channel 1 and 4 seconds stimulation on channel 2. By increasing the intensity the muscle contraction should be observed and light indicator beside the intensity knob should shine during stimulation, thus indicating current flowing through electrodes. The manual switch should be inserted without turning the stimulator off. Pressing and depressing the switch should toggle the stimulation between the channels. If the operation of the stimulator complies with the described procedure it checks OK, otherwise consult chapter 2.9. If the stimulator still does not check OK, have it checked by an authorised person.

2.7.2 Technical check

Technical check must be performed by a qualified person. A two-channel oscilloscope and two artificial loads (1.5 k Ω resistor) are required. The voltage should be measured on each resistor by oscilloscope. New batteries should be used for the test. Following the same procedure as described in chapter 0 one should observe the stimulating pulses on the screen. The shape of pulses should correspond to those represented on Fig. 4. The pulse duration and frequency should match the Technical characteristics (chapter 4). In case of discrepancy or malfunction contact an authorised person for re-check and eventual repair.

Leakage current is measured according to standard EN60601-1 clause 19. Ambient temperature must be between 21 and 25°C without humidity.

2.8 Battery Changing

Two 1.5V LR-6 (size AA) batteries are required for operation of ALT-2 stimulator. Rechargeable 1,24V battery cells of the same size may also be used. The battery compartment cover is positioned on the bottom of the rear side of the stimulator. Always replace both batteries with new ones.



Figure 5: ALT-2 stimulator with open battery compartment showing the position of batteries.

Turn both intensity control knobs to off position. Remove the battery compartment. Remove the old batteries. Insert a new pair according to the polarity shown in the bottom of the battery compartment.

The leaking of an old battery may damage the contacts. An exhausted battery should be removed from the battery compartment immediately. The batteries should also be removed when the unit is not used for a period longer than a week.

For the safety reasons the stimulator will not operate if batteries are removed and re-inserted while the stimulator is turned on. To resume the normal function the stimulator must be turned off and on again.

The red indicator on the front side of the stimulator provides the control when the device is on or off, and a battery control function. When the battery is depleted to a critical level, the red indicator will start flashing. In addition to flashing an audible alarm is set on. The function of such alarm is to warn the user, that there is about 10 minutes of safe operation left. This should give enough time to a standing or walking person to resume safe position and thus avoid possible collapsing due to sudden stimulation intensity drop.

2.9 Possible Malfunction of the System and Remedies

Absence of stimulation

Cause:

- missing or depleted battery
- “click” action required
- disconnected stimulating electrodes
- installed batteries with stimulator turned on

Remedy:

- install a new battery
- press and release the manual switch
- connect the electrode
- turn the stimulator off and on again

Weak stimulation in spite of maximum setting

Cause:

- depleted battery
- excessively dry electrodes
- self-adhesive electrodes do not stick well
- improper position of electrodes

Remedy:

- install a new battery
- wet the electrodes with water
- dispose of the electrodes and use a new pair
- reposition the electrodes

Unpleasant sensation before functional movement is achieved

Cause:

- excessively dry electrodes
- self-adhesive electrodes do not stick well
- improper position of electrodes
- irritated or wounded skin

Remedy:

- wet the electrodes with water
- dispose of the electrodes and use a new pair
- reposition the electrodes
- discontinue stimulation and consult the therapist

Maximum stimulation intensity at the lowest possible setting of the intensity knob

Cause: stimulator malfunction

Remedy: have stimulator repaired

Notification of Defects

If all of the above instructions have been observed and the stimulator is still not operating correctly:

Do not repair stimulator by yourself. Repairs should be performed only by an authorised person. In case of malfunction contact your supplier.

3 Instructions for the Therapist

3.1 Finding the Optimal Position of Stimulating Electrodes

Thoroughly moisten the water soaked electrodes with tap water before placement. Moisten them again when they have been used for more than 3 hours.

Large rectangular electrodes are intended for the electrical stimulation of knee extensor muscles. Place the lower rectangular electrode (black connection) just above the knee and the upper one (red connection) on the upper third of the knee extensor muscles, according to the intensity of muscular response. Fix the water soaked electrodes with elastic Velcro straps.



Figure 6: Paraplegic person during exercising program in lying position.

The small round electrode is used for the stimulation of peroneal nerve in order to achieve dorsal flexion in the ankle joint and reflex flexion in the knee and hip joints. Attach the electrode above the nerve trunk between the fossa poplitea and the head of fibula. Change the electrode position to achieve the best functional movement. Proper position of the round electrode should be determined by the physiotherapist. The peroneal nerve can be stimulated only when the lower large rectangular electrode (black connection) is also attached to the extremity.

Alternating dual channel stimulator ALT-2 can also be used for strengthening of other lower and upper extremity muscle groups. Correct placement of the electrodes along

the muscles should be determined initially. A correct size electrodes should be used. Smaller electrodes are used for the stimulation of smaller muscles and larger electrodes are used for stimulation of larger muscles or muscle groups.

3.2 Muscle Strengthening

The muscle strengthening program of the knee extensor muscles is usually performed with a patient in the supine position. Place a pillow under the knees to bring the lower extremities in a slightly flexed position. Place the electrodes and connect them with the stimulator.



Figure 7: Paraplegic person during exercising program in seating position.

Apply only the two large rectangular electrodes (channel 1) for the strengthening program. Connect the electrode cable to the stimulator only when the electrodes have been attached to the muscle. Do not connect the manual switch cable. The cyclic mode of the stimulator ALT-2 is achieved with the repetition of 4 s trains of stimulation pulses and 4 s pauses. Make sure that both stimulation channels are switched off (both intensity adjustment knobs are in the extreme left positions) before connecting the electrode cable. Switch on the stimulator by turning knob “1” to the right and slowly increase the stimulation intensity until muscular contraction followed by knee extension occurs. With a very weak muscle, initially a complete knee extension will not be achieved even with maximal stimulation intensity. However, a visible and quite strong muscular contraction is required.

During the first week, muscle training should not exceed half an hour daily. Increase the stimulation intensity during the strengthening, if muscular contraction or range of motion decrease. Prolong the duration of strengthening for half an hour every week until the strengthening program reaches a minimum of two hours. The program can be divided into two parts, e. g., one hour of stimulation in the morning and another hour in the afternoon. The patient can read or perform other activities during the stimulation. The strengthening program can also be performed in a sitting position in a wheelchair.

Strengthening by electrical stimulation is particularly recommended in paraplegic and tetraplegic persons: sustained contractions not only strengthen the muscle but also decrease its fatigue, increase blood circulation, prevent formation of pressure sores, prevent or decrease contractures and spasticity.

At the end of the daily strengthening program, first switch off the stimulator. Disconnect the electrode cable by pulling out the plug. Only then, remove the electrodes.

3.3 Standing-up

Stimulator ALT-2 can usually be applied for the functional standing-up in paraplegic persons, while standing and gait can follow after the strengthening of atrophied paralysed muscles. Strengthening is not required in rare persons with sufficiently strong spasticity to preserve the muscle bulk. The first stimulated activity is standing up from a sitting position. In several paraplegic persons the stimulation is not strong enough and requires the help of upper extremities. Standing up is initially practised on parallel bars, similar stands, or suitable support at home. Electrodes are placed on both thighs, the same as in strengthening. Manual switches are mounted on a support close to the hands. Manual switch cables are connected to the stimulators. Adjust the stimulation intensity knob "1" to a value established before which produces a muscular contraction of adequate strength. When turning on the stimulator with manual switch being connected, no stimulation occurs on any channel. The stimulation starts after the manual switch has been shortly pressed and released for the first time.

Sit on the edge of the wheelchair with the toes behind the knees and with the trunk leaning forward. Grab the support and by quick pressing the manual switches (just a "click") start the stimulation and stand up with the help of stimulation. The next step is to stand up with a walker or a crutch in one hand, holding on to a firm piece of furniture (e. g. table) with the other hand. The described method is not the only one. The stimulator can be switched on and the stimulation started in the sitting position with extended lower limbs. Standing up with extended lower limbs is the same as with mechanical braces. Sitting down is achieved by pressing both manual switches and stopping the stimulation on channel 1.



Figure 8: Paraplegic person standing-up from the wheelchair using two ALT-2 stimulators.

3.4 Standing

A paraplegic person can stand, thanks to the sustained stimulation of muscles, from one minute to several hours, depending on fatigue and muscular ability. Posture influences the duration of standing, therefore, previous physical therapy in the preparation for standing up and standing is important. Prolong the initial short standing period to one hour. Pay attention to the correct position of extended lower limbs with the trunk slightly leaning backwards (lumbar lordosis). Correct posture diminishes the force in the knees and increases the effectiveness of electrical stimulation.

Increase the intensity if the knee extensors start to fatigue (slightly bent knees). In paraplegic persons standing is a therapeutic activity which prevents the weakening of muscles, formation of contractures and pressure sores, increases blood circulation in the lower extremities and enhances the functioning of internal organs (e. g. regular excretion).

3.5 Daily Activities

Typical daily activities requiring standing are reaching for objects at higher levels and transferring from and to the wheelchair. Reaching for high objects can be done, for instance in the library, kitchen, supermarket, at the bank or post office counters; it can be used for ringing doorbells, calling elevators, turning on lights, opening and closing windows. The ALT-2 stimulator can be effectively used for the transfer from the wheelchair in a narrow bathroom not designed for the paraplegic person.



Figure 9: Paraplegic person standing with two ALT-2 stimulators.

3.6 Gait

After appropriate training of standing many persons can achieve walking with stimulation. The first steps must be executed under the supervision of a physiotherapist qualified to teach standing and gait with electrical stimulation. Only this way the correct gait can be achieved.

Initially, the paraplegic person walks with the support of a walker. Both manual switches are mounted on at the handles. The appropriate flexor response is established by depressing the manual switch and moving the small round electrode along the peroneal nerve. Gait consists of the double support phase and a swing phase. During the support phase, both knee extensor muscles are stimulated simultaneously. The lifting of the lower extremity at the end of the support stage is achieved by depressing the manual switch on the walker or crutch. Thus, the stimulation of quadriceps muscle is interrupted and the stimulation of the peroneal nerve is switched on, evoking flexor response, producing the lower extremity flexion in hip, knee and ankle. The swing lasts as long as the manual switch is depressed. When the switch is released, the stimulation of knee extensors is switched on again.

When the paraplegic person is able to reliably walk with the support of a walker, the training of gait with crutches can begin. The manual switches are mounted on both crutch handles. The learning of gait with crutches must be executed under the supervision of a physiotherapist.



Figure 10: Paraplegic person walking with two ALT-2 stimulators using walker.

3.7 Notes

- Electrodes should be applied on predetermined sites on the skin.
- Stimulation intensity should be increased gradually.
- Stimulation should not be applied with the electrodes placed on more than one extremity (hand-hand, hand-leg, etc.).
- Stimulation should not be applied over an open wound, a cut or other skin lesion.

With every day continual use, the electrodes should be detached at least daily. Should even in spite of this safety precaution some hypersensitive patient develop skin irritation under the electrodes, treat it as a skin lesion. Stimulation should be discontinued during the treatment or the electrodes should be applied at some other site (e.g. on the muscle).



Figure 11: Paraplegic person walking with two ALT-2 stimulator using crutches.

4 Technical Characteristics

Output current on each channel separately	0 - 180 mA (1.5 k Ω load)	adjusted by the patient or therapist
Waveform	current output, rectangular, balanced, asymmetrical, biphasic pulses	see Fig. 4.
Frequency	20 Hz	fixed
Pulse duration	0.25 ms	fixed
Mode of action	manual controlled or 4s / 4s intermittent	
Battery	2 x 1.5 V LR-6 alkaline battery, or 2 x 1.24 V rechargeable NiCd accumulator (optional)	LR-6 (size AA)
Dimensions (HxWxD)	115 x 60 x 21 mm	
Weight	136 g	batteries included

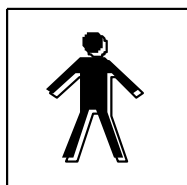
5 Symbols

SWITCH

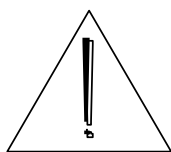
This symbol shows the position of the plug, where the manual switch connector is to be plugged in.

ELECTRODE

This symbol shows the position of the plug, where electrode cable connector is to be plugged in.



This is a B type equipment with an F type applied part (IEC 601-1 subclause 2.2.25). B type equipment provides particular degree of protection against electric shock, particularly regarding: allowable leakage current, and reliability of protective earth connection (IEC 601-1 subclause 2.2.24). The F type applied part when applied part isolated from all other parts of the equipment to such degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth (IEC 601-1 subclause 2.1.7).



This equipment is capable of delivering output values in excess of 10 mA r.m.s. or 10 V r.m.s. averaged over any period of 5 seconds.

CE 0125

This is a certified CE marked product. It conforms according to the Council Directive 93/42/EEC Annex IV and Annex VII. The EC verification according to Annex IV was carried out by LGA (the notified body no. 0125). The ALT-2 stimulator is produced in accordance with standards: IEC 601-1:88+A1:91+A2:95 (EN 60601-1:90+A1:93+A2:95) and IEC 601-2-10:87.

6 Literature

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Manufactured by:

Jožef Stefan Institute

Jamova 39

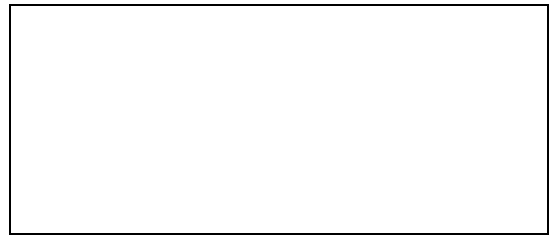
SI-1000 Ljubljana

Slovenia

tel.: +386 1 477 39 00

+386 1 477 37 37

Official representative:



email: stimulatorji@ijs.si