

Functional Electrical Stimulator System

Model 2000 Alt-2 Professional Kit Model 1000 Alt-2 Personal Kit Model 500 Alt-2 Personal Kit

CE

Introduction

The ALT-2 stimulator is a high current output functional electrical stimulation (FES) device designed for muscle strengthening, 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.

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
- orthopedic rehabilitation patients after musculoskeletal trauma or surgery, or any other patients, who suffer from weak or atrophied muscles due to inactivity.

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

Candidates

- incomplete and complete SCI patients
- orthopedic patients (e.g. after immobilizations, after total hip replacement)

Special considerations

- Stimulated muscles subject to rapid fatigue
- Severely limited muscle endurance
- Osteoporosis
- Joint and tendon contractures
- All general contraindications for FES application

Stimulator features

The Alt-2 stimulator permits alternating intermittent trains of stimulating pulses in two channels. The repetition rate is 20 pulses per second and the pulse duration is 250 microseconds. These parameters were optimized in order to provide smooth tetanic muscle contraction and to minimize muscle fatigue. They are preset by the manufacturer and cannot be changed. In each channel respectively, the intensity of biphasic charge balanced stimulating pulses can be set between 0 and 150 mA.

Two modes of operation are available. With manual switch disconnected, the intermittent mode of operation is selected. Four-second trains of stimulating pulses alternate between the two channels. With the manual switch connected, the manual operation mode is selected. If the manual switch is released, continuos stimulation appears on the first channel and no stimulation on the second channel. When the manual switch is depressed the stimulation on the first channel is discontinued and the stimulation on the second channel appears for as long as the manual switch is depressed.

The Alt-2 stimulator has a unique feature, that enables easier FES assisted standing-up. If the stimulator is turned on with the manual switch already connected, there will be no output on either channel until a short "click" is performed on the manual switch. After the "click", when the manual switch is released, the stimulating pulses of preset intensity appear on the first channel. Thus, the proper positioning of the patient for standing-up is enabled, before the stimulation of knee extensors is activated.

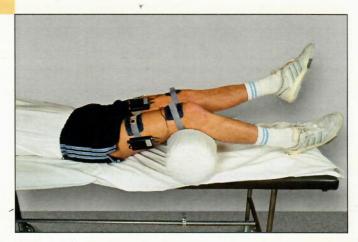
The stimulator is powered by two AA size alkaline batteries or by rechargeable NiCd accumulators. The Alt-2 device is small and light weight, and can be easily attached to the belt or to electrode fixation strap.

WARNING: The ALT-2 stimulator is a high output current device. In patients with preserved sensation extreme caution should be taken while increasing the stimulation intensity. Never place the electrods on thorax or neck.

Alt-2 stimulator in muscle strengthening program

Atrophy of skeletal muscle occurs whenever muscle is denervated, that is, when the motor axons to muscle degenerate. Atrophy will also occur when 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 Alt-2 stimulator. In complete central nervelesions Alt-2 stimulator enables activation of paralyzed muscles and thus prevents their atrophy and development of other symptoms associated with muscle disuse (e.g. contractures, osteoporosis, blood circulation problems).

In orthopedic patients a disuse atrophy of muscles appears after prolonged limb or joint immobilization. After surgical treatment (e.g. total hip replacement, osteosynthesis) partial peripheral nerve lesions might occur. In such cases the Alt-2 stimulator is a convenient tool to enable the patient improve contraction force and increase endurance of the affected muscle. Application of



Alt-2 stimulator application in knee extensors strengthening program

Alt-2 stimulator may be very convenient for muscle strengthening while little or no load to the bone is allowed. The muscle strengthening program of the knee extensor muscles is usually performed with a patient in sitting or in supine position. Similar procedure is used in stimulation of any other muscle. Patient should be placed in supine, prone, or sitting position according to the function of the stimulated muscle. In patients with preserved sensation not only sufficient muscle contraction, but also tolerance of the stimulation is a guideline for setting the intensity of stimulation.

ALT-2 stimulator for standing-up and standing

Verticalization of SCI patients has many beneficial effects to the patient (e.g. improved bladder and bowel function, prevention of osteoporosis and tendon contractures). Traditional approaches to produce standing in SCI population have included the use of passive knee-ankle-foot orthoses applied to the lower extremities and mechanical balance devices used in conjunction with upper extremities to provide balance. In such systems the muscles of the shoulders and upper limbs provide the power for standing and sitting activities. However, applying and removing bilateral braces is time consuming and therefore, the user rejection rate is relatively high. The Alt-2 stimulator represents a small size and light weight alternative to mechanical bracing with additional beneficial-side effects (e.g. improved blood circulation, muscle atrophy prevention).

Standing-up: Stimulator ALT-2 can usually be applied for the functional standing-up in paraplegic persons, while standing and gait can follow after strengthening of atrophied paralyzed muscles. The first stimulated activity is standing-up from a sitting position. Additional help of upper extremities is required in order to synchronize movement of the trunk during standingup and to maintain balance. Standing-up is initially practiced in parallel bars, in similar stands, or with suitable support at home. Two Alt-2 devices are required for standing-up of a complete SCI patient. Electrodes are placed on both thighs, the same way as during strengthening program. Sitting down can be achieved in two ways: by pressing both manual switches, thus stopping the stimulation and perform a sort of controlled collapsing into the wheelchair, or with the stimulation on, performing it the same way as with mechanical bracing. Standing: A paraplegic person can stand, due to the sustained stimulation of muscles, from one minute to several hours, depending on fatigue and muscular ability. For paraplegic persons standing is a therapeutic activity which prevents weakening of muscles, formation of contractures and pressure sores, increases blood circulation, improves sexual function and quality of sperm in male patients, prevents osteoporosis and arthrosis, and enhances the functioning of internal organs (e. g. regular excretion).

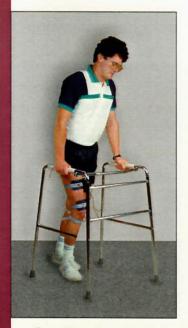


Alt-2 stimulator application for standing-up



Standing with Alt-2 stimulators

ALT-2 stimulator for gait



Gait with walker using Alt-2 stimulators



Gait with crutches using Alt-2 stimulators

After appropriate training of standing many complete SCI patients 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. Initially, the paraplegic person learns walking suspended in parallel bars. Later, a walker and finally crutches can be used. Two Alt-2 devices are required for walking. The first channel is used for knee extensor stimulation, while the second channel is used for flexor response stimulation on the peroneal nerve. Both manual switches are mounted on the handles. Gait consists of double support phase and 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 phase is achieved by depressing the manual switch on that side. Thus, the stimulation of knee extensors is interrupted and the flexor response is evoked, resulting in the hip, knee and ankle flexion. 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 and the double support is resumed.

Daily Activities: Reaching for objects at higher levels and transferring from and to the wheelchair are typical daily activities requiring standing and gait,. By using Alt-2 stimulators, 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 transfer from the wheelchair in a narrow bathroom not designed for a paraplegic person.

Literature

Cybulski GR., et al.: Lower Extremity Functional Neuromuscular Stimulation in Cases of Spinal Cord Injury, Neurosurg., Vol. 15, pp. 132-146, 1984. Hooker SP., et al.: Physiologic Effects of Electrical Stimulation Leg Exercise Training in Spinal Cord Injured Persons, Arch Phys Med Rehabil, Vol. 73, pp. 470-476, 1992. Kralj A., T. Bajd: Functional Electrical Stimulation for Standing and Walking After Spinal Cord Injury, CRC Press Inc., 2000 Corporate Blvd., N.W., Boca Raton, Florida, 1989.

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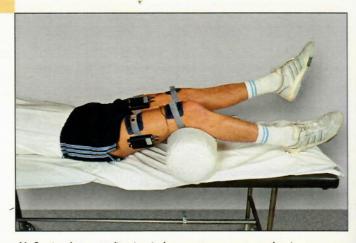
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System Components

Alt-2 Model 2000

2 Alt-2 stimulators

3 packages of disposable electrodes

6 durable electrodes

4 manual switches

4 electrode connective cables

6 Velcro straps

4 rechargeable batteries

Battery charger

Storage case

Operations manual

Alt-2 Model 1000

2 Alt-2 stimulators

3 packages of disposable

electrodes

2 manual switches

2 electrode connective cables

2 Velcro straps

4 batteries

Leather storage case

Operations manual

Alt-2 Model 500

Alt-2 stimulator

2 packages of disposable electrodes

Manual switch

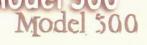
Electrode connective cable

Velcro strap

2 batteries

Leather storage case

Operations manual







Alt-2 Model 500

Alt-2 Model 2000

Technical characteristics

Output current on each channel separately	0 - 150 mA (0 - 1000 Ω load)	adjusted by the patient or therapist
Waveform	current output, rectangular, balanced, asymmetrical, biphasic pulses	
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 alkaline battery, or 2 x 1.24 V rechargeable NiCd accumulator (optional)	AA cell (R6 - IEC)
Dimensions (HxWxD)	100 x 57 x 24 mm	
Weight	140 g	batteries included