

# NEW STIMULATORS FOR CUTANEOUS STIMULATION

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## ABSTRACT

Basing on the previous experience in the development of cutaneous stimulators, three new stimulators have been designed for different fields of application.

Therapeutic electrical stimulator (TES) is intended for the use in clinical conditions. It provides several types of stimulation pulses such as tetanic, peripheral and diadynamic, with the possibility of the offset for the last one.

Stimulator TES can operate in a continuous or cycling mode and has a built-in clock. Peak detector measures the true amplitude of the output stage, which can be set either as a current or a voltage one, with changeable polarities. Attention is paid to the safety of the patient, since every time that the TES' operating mode is changed, the output amplitude must be set to zero. TES can be powered from the mains, an accumulator or batteries.

Stimulator for the correction of scoliosis has been designed. Care has been taken for the shape of the stimulation bursts so that patients are not disturbed during sleep. The output is controlled by a signal lamp. A significant voltage drop of the batteries results in automatic switch-off of the stimulator which in turn indicates the battery changing.

For the relief of pain, a small portable stimulator has been developed providing rectangular current pulses. Linear slide knob enables linear control of the amplitude setting. Stimulation can be continuous or externally controlled.

All these stimulators have been designed after a profound study of most of the existing stimulators of their type and careful selection of parameters has been performed. The stimulators have been evaluated and preliminary results have been obtained.

## INTRODUCTION

Three new cutaneous electrical stimulators have been developed for Yugoslav producer of medical devices Gorenje-Velenje, as the logic continuation of the work started years ago when the first three stimulators were designed for the same producer. Those first stimulators were : Therapeutic Stimulator PLS-4 (commercial name Unifes) which is designed for home use without direct supervision of medical personnel, Functional electrical stimulator FESE-h3 (Hemifes) that provides hand opening movement in hemiparetic patients and orthotic electronic underknee peroneal stimulator Fese-L2 (Mikrofes) for rehabilitation of hemiplegic patients' gait (1).

Basing on the experience, new stimulators have been designed for three different fields of application : The Therapeutic electrical stimulator TES, the stimulator for the correction of scoliosis and the cutaneous stimulator for the relief of pain.

## THERAPEUTIC ELECTRICAL STIMULATOR TES

Starting from our experiences in the development of cutaneous stimulators an inquiry has been made in the clinical and rehabilitation centers of Slovenia to find the requirements and the needs for a general purpose stimulator. On these grounds we decided to develop a small (25x28x8 cm) portable therapeutic stimulator which could be powered either from the mains, an accumulator or from batteries. At the same time this electromedical device should have a large variety of stimulation modes and parameters, and should be applicable in clinical environment and electrotherapy departments. The development should take into consideration all IEC international standards dealing with the patient's safety.

Following the above requirements a stimulator with the following features has been developed (Fig. 1).

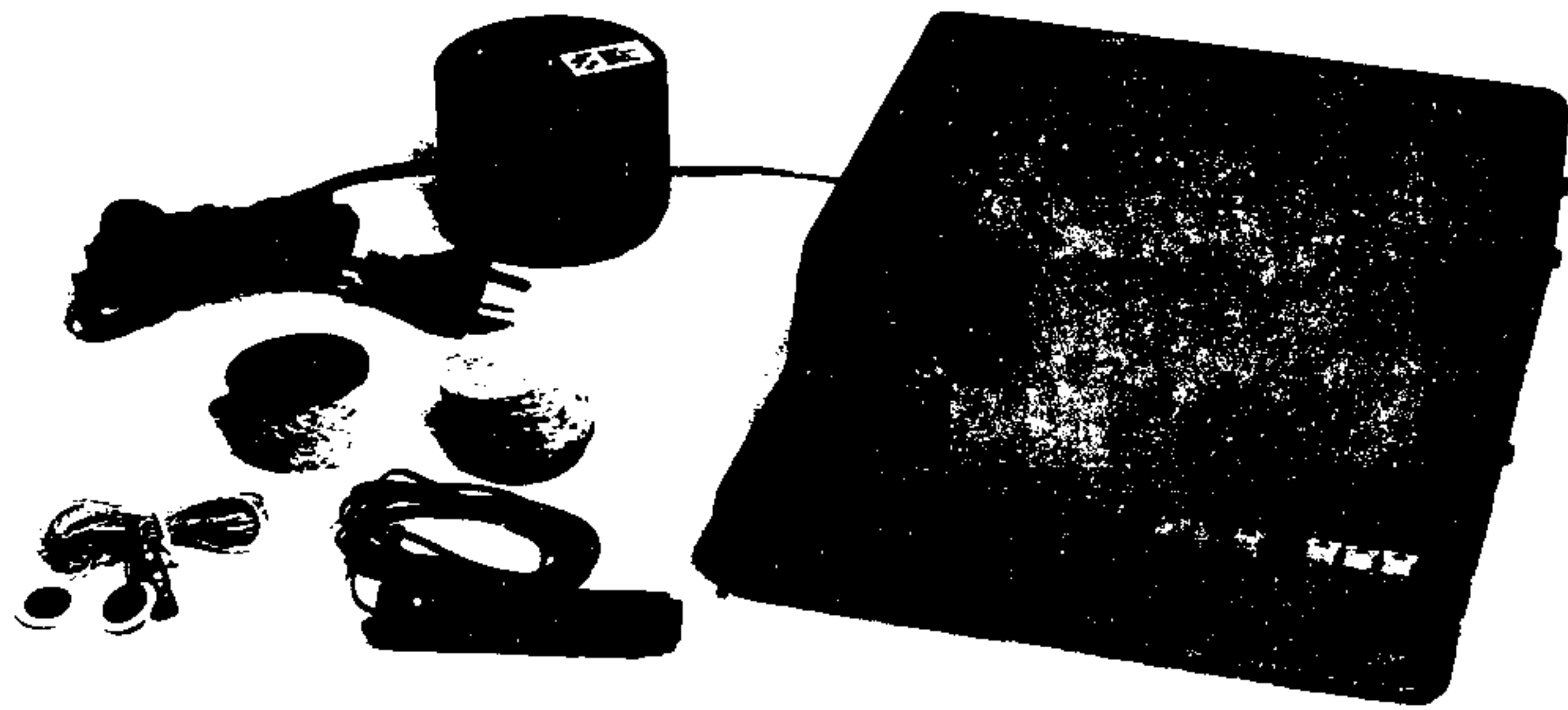


Fig 1: Therapeutic electrical stimulator TES with power supply unit, electrodes, push button switch for external control, and electrode cable.

- continuous rectangular tetanic pulses with repetition rate from 20 to 200 Hz and pulse duration from 2 to 2.5 ms,
- continuous rectangular long "peripheral" pulses with repetition rate from 0.6 to 6 Hz (two options exist: 0.3 to 3 Hz, 1.2 to 12 Hz) and pulse duration from 15 to 150 ms,
- trains of tetanic pulses with the possibility of train duration setting and setting of the pause between trains (1 - 8 sec),

- exponentially increasing pulse-train of tetanic pulses or exponential single "peripheral" pulse,
- four modes of "diadynamic" pulses:
  - MF - monophasic fixed (50 Hz)
  - DF - diphasic fixed (100 Hz)
  - CP - rhythmic syncope (cycling: 50 Hz, 100 Hz)
  - RS - court periods (cycling: 50 Hz, pause)
- galvanic current which is used together with "diadynamic" pulses (max. amplitude is 10 mA),

TES's output stage can operate as voltage stage (max. amplitude is 120 V) or current stage (max. amplitude is 45 mA),

- push button switch enables the polarity changing,
- external control is possible with hand triggering of single "peripheral" pulse or tetanic pulse train. In second version all stimulation modes are on as long as the push button switch of the external control is pressed.

In the Therapeutic Electrical Stimulator several electronic circuits are build-in: electronic clock enables setting duration of the therapy from 1 to 30 minutes, special electronic logic turns-off the stimulation, when the ratio between pulse-width of "peripheral" pulse and pause between pulses is one, acoustic feedback signal is build-in to indicate either the whole train of tetanic pulses or a single "peripheral" pulse. The same acoustic signal also indicates the end of a preset electrotherapy. Peak detector measures peak value of amplitude (voltage or current) directly on patient's electrodes. Two versions of display have been developed: LCD display and 16 Led diodes set in line.

The reliability of operating is of major importance therefore only high quality components have been carefully selected. Attention has been also paid to the safety of the patient. Every time when the therapist wants to change stimulation mode, he must set the output amplitude to the initial position. Just in this case the changing of stimulation modes is possible.

Four prototypes have been in the clinical evaluation and the general opinion is that TES is a useful for electrotherapeutic application.

## THE CUTANEOUS STIMULATOR FOR THE CORRECTION OF SCOLIOSIS

A cutaneous stimulator for the treatment of progressive scoliosis has been developed (Fig. 2). It is designed as a by-the-bed stimulator with the dimensions 19 x 16 x 6.5 cm and is powered from four 1,5 V battery cells with the maximum current drain of 70 mA. A red LED indicates when the stimulator is switched on. When the battery voltage drops under the operational value, the stimulation is switched off automatically and the same LED starts blinking.

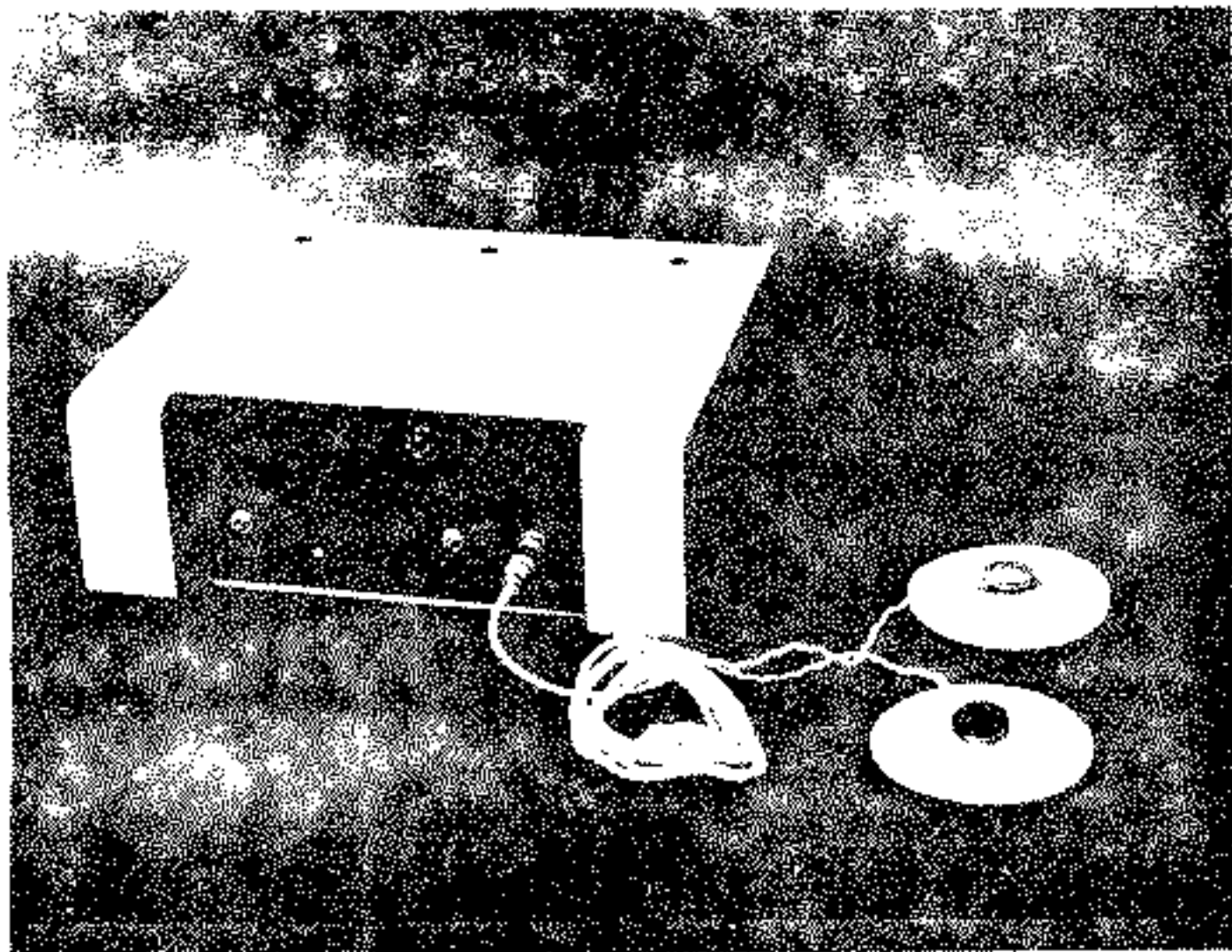


Fig. 2: The cutaneous stimulator for the correction of scoliosis

The stimulator exhibits a voltage output in the region from 0-120 V. A current limiter is incorporated in the output stage that cuts off the current at 100 mA. The pulse-width can be set between 0,1 and 0,5 ms with a knob on the rear panel. The frequency is normally set to 30 Hz but can be changed to 20 Hz or 40 Hz with a switch inside the instrument.

Stimulation appears according to a preset program with six seconds of stimulation and six seconds of pause. The rise and the fall time of pulse trains is two seconds. Stimulation can be kept continuous by pressing a button on the front panel. The stimulation on-time is indicated by a green lamp when the external load is less than 10 Kohm.

Fifteen stimulators are presently being tested at the Clinical center of Ljubljana for the evaluation and for comparison with similar devices (ref. 2).



## STIMULATOR FOR PAIN RELIEF PRS4

Electronic stimulator for relief of pain PRS4 has been designed for electrical stimulation of sensoric nervous pathways to prevent or suppress the transmission of pain to cortex by processes in the central nervous system. The stimulator has been intended for the relief of accute, chronic, postoperative, as well as labour pain.

Its design enables its use both in clinical and home environments. Medical personnel can select parameters of stimulation in wide ranges or can preset them for each patient individually so that unwanted changes of parameters can not bother the patient. Patient only switch the device on and off and set the intensity of stimulation besides applying stimulation electrodes. After initial explanations of the principle of stimulation, the device can be used in normal every day's environment of the patient.

The stimulator includes in itself small size and energy requirements, portability, simple handling and battery powering, as well as possibilities of wide settings of stimulation parameters, remote control, indication of stimulation pulses and control of the batteries. Optionally, the ranges of frequency and pulse width can be further enlarged to enable the stimulator for research work and to provide the patient with equal device for clinical and for his home environment. Due to the psycho-somatic nature of pain, and for it has been proved quite important not to neglect this psychological aspect.

Different kinds and sizes of surface stimulation electrodes have been tried with the stimulator. Its current output enables equal constant currents for the loads from 0 Ohms to 3 kOhms, i.e.: almost any kind of electrodes can be connected to the device with amplitude changes without risks, provided safe current densities are used.

With the use of different battery power packs, the stimulator can be used as a small portable or as a desk top clinical device with long battery life.

The stimulator provides constant current pulses up to 50 mA. It can operate continuously or can be controlled by remote switch. The ranges of repetition frequency from 10 to 150 Hz and pulse width from 0.1 to 0.5 msec can be optionally larger: the frequency range from 10 to 250 Hz and the pulse width range from 0.1 to 1 msec have been intended for clinical research.

More than 20 prototypes has been succeseffuly evaluated in the clinical environment for the relief of chronic pain and for the relief of pain during delivery respectively (3).

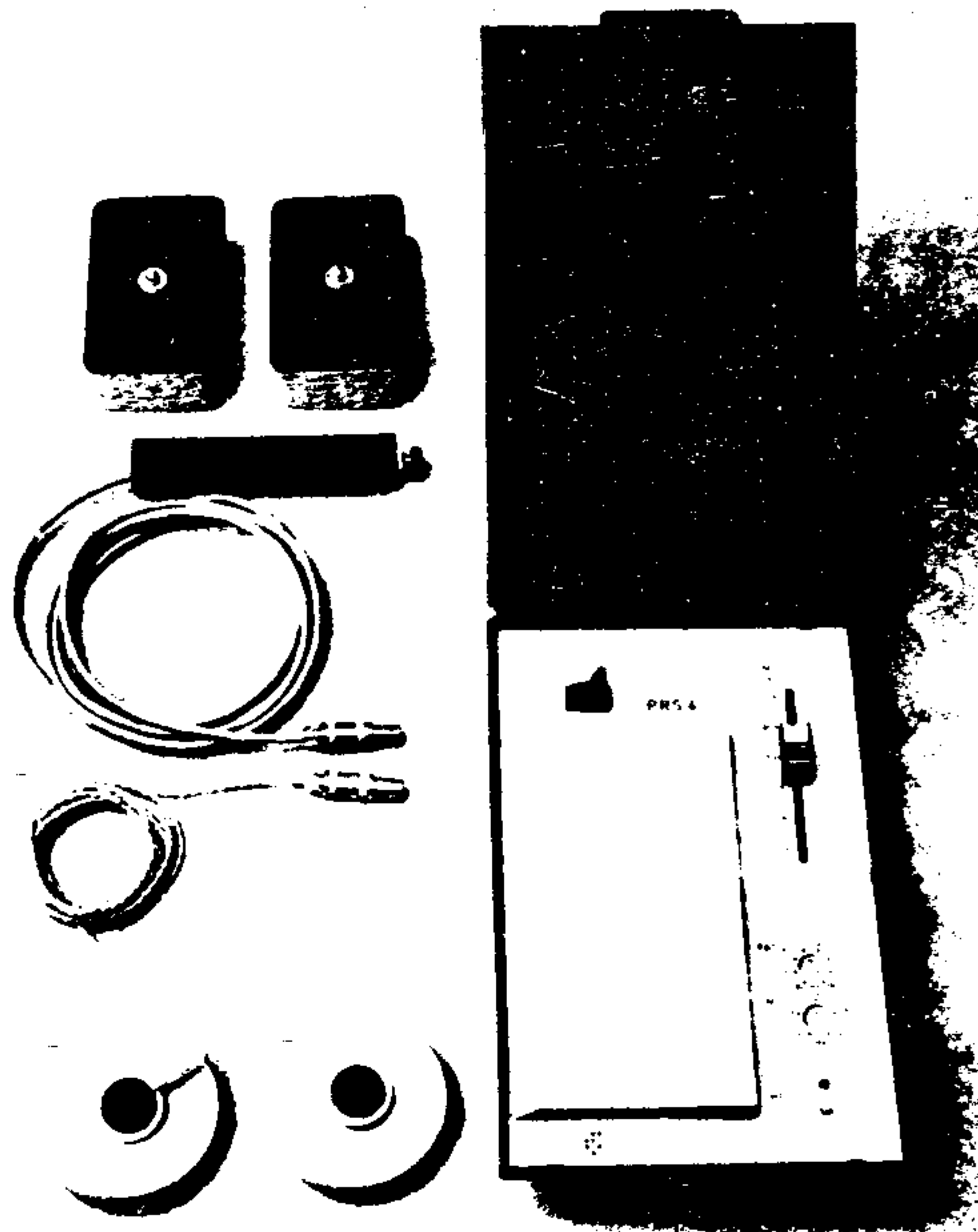


Fig. 3: Stimulator for pain relief PRS4

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