# Battery-powered implantable nerve stimulator for chronic activation of two skeletal muscles using multichannel techniques

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## SUMMARY

Chronic activation of skeletal muscle is used clinically in representative numbers for diaphragm pacing to restore breathing and for graciloplasty to achieve fecal continence. In both applications the skeletal muscle is extremely strained; muscle fatigue is consequently one of the exciting problems associated with these techniques. Various stimulation methods have been developed to improve on this. It was our aim to make some of these stimulation methods applicable for the above FES applications by a battery-powered nerve stimulator.

The implantable nerve stimulator can be used for activating two skeletal muscles. Stimulation of the motor nerve is achieved by either single channel or multichannel methods with up to 4 electrodes for each nerve. Carousel stimulation, sequential stimulation as well as optimized pulse trains can be implemented. All stimulation parameters can be adjusted with a high resolution using an external programmer. The system can be used for graciloplasty as well as for diaphragm pacing.

Nerve pacing is effected by ring-shaped stainless-steel electrodes. These epineurial electrodes are used clinically in the ”Vienna Phrenic Pacemaker”. The multichannel pulse generator is hermetically sealed in a titanium case and powered by a Lithium Thionyl Chloride battery. For diaphragm pacing we calculated a life span of 4.1 years, based on the stimulation parameters used by us clinically. The size of the pulse generator is 65 x 17 mm (diameter x height); it weighs 88 g.

## STATE OF THE ART

Chronic activation of skeletal muscle is used clinically in representative numbers for diaphragm pacing to restore breathing and for graciloplasty to achieve fecal continence. In both applications the skeletal muscle is extremely strained; muscle fatigue is consequently one of the exciting problems associated with these techniques. In clinical use the phrenic pacemaker is set to an inspiration rate of 10/min at a stimulation duration of 1 s over 24 hours per day. The gracilus muscle for treatment of fecal incontinence is stimulated continuously over several hours each day.

For respiration in humans electrical pacing systems have been developed by three different groups /1/. These systems consist of electrodes placed on the phrenic nerves which are connected by leads to an implanted stimulator. The single or multichannel stimulators are powered and controlled via an external high frequency transmitter from a portable programmer. The programmer coordinates the overall timing, and stores the received stimulation parameters. For graciloplasty, battery-powered single channel implants, with the electrodes usually positioned near the motor point of the skeletal muscle, are currently in use /2/. Activation of two muscles is not yet applied clinically.

Over the last few years our group has worked on developing a modular stimulation system usable for a variety of applications. Important components of the stimulation system, such as the implant case, the main module of the implant electronics, the stimulation electrodes, and the hardware of the programmer unit, remain the same in all applications. Useful applications and the limitations of such a battery-powered implant have been described in /3/ on the basis of first calculations and prototyping. Additionally, the first specific application of this modular concept, i.e. an ECG-triggered stimulator for cardiac assistance by skeletal muscle, has already been tested in an animal study and produced extremely satisfactory results.

The implantable device presented here was developed for use in electrophrenic respiration (EPR) and in graciloplasty. In developing the stimulator we had set ourselves the following goals: The system should allow the implementation of all stimulation techniques used so far in diaphragm pacing in humans (single channel or multichannel methods such as carousel stimulation /4/ and sequential stimulation /5/). The use of external devices should be limited to the time necessary for programming in order to maximize the patient's freedom of movement. Additionally, the system should allow alternating stimulation of two skeletal muscles as a further improvement in graciloplasty.

## MATERIAL AND METHODS

The stimulation device is composed of a programmer with a transmitter unit, an implantable multichannel stimulator, and nerve pacing leads (Fig. 1).

The multichannel stimulator is powered by a Lithium Thionyl Chloride battery (WG8602, Wilson Greatbatch Ltd. NY, USA) and works as an independent system in the body. It includes an eight-channel output stage, a transmitter unit, and a controller unit. A microcontroller serves as the central unit of the controller. The number of pulses in one burst, burst frequency (1÷50 Hz), pulse width (0.2÷1 ms), pulse amplitude (0÷4 mA), and current active output are set by the controller unit. All parameters and functions are programmable via the bidirectional telemetry circuit. The eight output stages provide a constant current pulse, each output channel can be switched as anode or cathode or can be deactivated.

The multichannel pulse generator is hermetically sealed in a titanium case and powered by a Lithium Thionyl Chloride battery. Its size is 65 x 17 mm (diameter x height) and it weighs 88 g. Nerve pacing is effected by ring-shaped stainless-steel electrodes. These epineurial electrodes are used clinically in the ”Vienna Phrenic Pacemaker” /4/.

The stimulation data are input using a laptop computer (IBM-PC or compatible) instead of a specially designed programmer. A graphical user interface facilitates the setting and modification of parameters and reduces training time. Each modification of the parameters is stored automatically and can be processed in conjunction with additional data such as respiration flow, or the patient's medical history. Data are transferred between the PC and the implanted pulse generator in both directions by a radio-frequency transmitter unit linked to the serial port (RS-232) on the PC. The transmission link operates over a vertical displacement of up to 50 mm at a data rate of 1200 bit/s and a carrier frequency of 100 kHz.

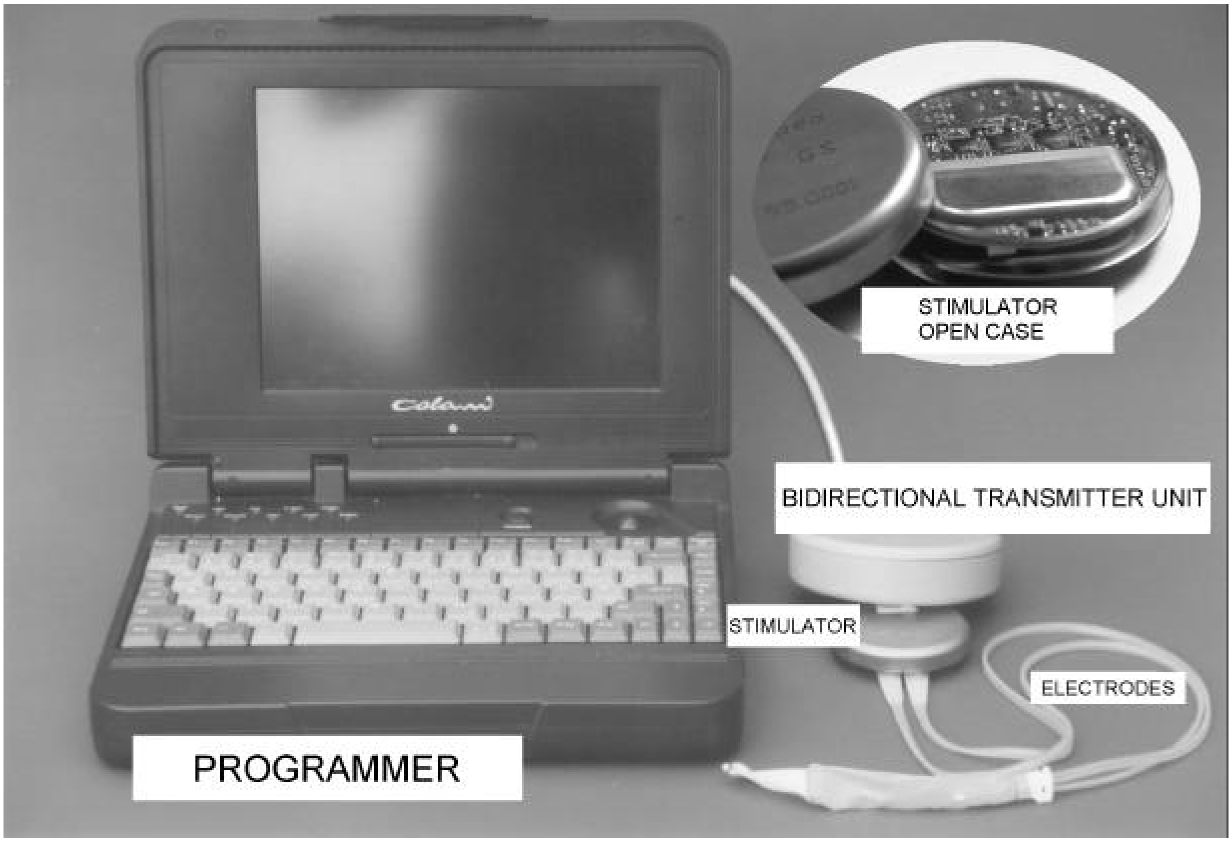


Fig.1 stimulation device, programmer (laptop computer), transmitter unit, implantable multichannel stimulator, and nerve pacing leads

## RESULTS

This implantable neurostimulator can be used for activating two skeletal muscles. Stimulation of the motor nerve can be achieved by either single channel or multichannel methods with up to 4 electrodes for each nerve. The stimulation wave-form can be adapted to the requirements of EPR and of graciloplasty. Two skeletal muscles can be activated simultaneously, alternately or in un-interrupt mode.

### Diaphragm pacing to restore breathing

The stimulation system allows implementation of all stimulation techniques currently in use in EPR, which differ greatly from each other in their use of either single channel or multichannel electrodes and in their selection of impulse parameters. Among the three groups that have developed phrenic pacing systems the group from Yale (USA) uses unipolar stimulation for each nerve with a remote indifferent electrode at low stimulation frequencies of 7-10 Hz and inspiration rates between 7-10/min. The other two groups use multichannel techniques with 4 bipolar electrodes applied to the phrenic nerves. The group from Tampere (Finland) implements sequential stimulation /5/, the active electrodes are changed for each impulse and the stimulation frequency decreases from 25 to 16 Hz during the inspiration burst. The Vienna (Austria) group implements carousel stimulation /4/, the active electrodes are changed after each inspiration burst, a constant stimulation frequency of 26 Hz is used. Furthermore, the stimulation current increases during an inspiration burst from the threshold current to adequate maximum current to achieve a smooth contraction.

All these functions are mastered by the developed device, which also allows all parameters to be adjusted within a large range with a high resolution. As an additional feature optimized pulse trains, a stimulation technique published in 1980 by Zajac FE and aimed at increasing fatigue resistance, can be implemented.

Graciloplasty for fecal continence

The developed device allows the application of all advanced stimulation techniques described above for graciloplasty, too. As a further improvement of this particular FES application the system makes it possible to alternately stimulate two skeletal muscles.

## DISCUSSION

This stimulation system can be used for graciloplasty and for diaphragm pacing. The developed device is based on a modular system architecture, which is advantageous for several reasons. Time and effort necessary for developing a specific application are reduced, by integrating components already tested, such as the implant case, the risk of design errors is reduced.

The integration of different stimulation techniques in one stimulation system has to be considered the main achievement in the development of this device. Due to its versatility the stimulator is especially suitable for in vivo studies, in particular for the investigation of new methods for optimizing muscle output by electrical stimulation. Furthermore, all parts of the implant that have direct contact with body tissue use the latest pacemaker technology (titanium, silicone-rubber, epoxy resin) and have been tested in animal studies.

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