16 CHANNEL STIMULATION SYSTEMS FOR THE USE OF FES AND RELATED APPLICATIONS

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ABSTRACT

A new modular stimulation system for use in Functional Electrical Stimulation (FES) of both upper and lower extremities is described. The system has been designed to meet the requirements of different areas of application, as muscle testing and training, FES induced movements and treatment of spasticity, by only exchanging specific modules. The modularity simplifies the adjustment of the stimulation system to the handicapped patients with different forms of paralyses and specific needs. According to these applications the stimulators are equipped with up to 16 stimulation channels. These can serve surface or percutaneous electrodes. For this reason output stages deliver constant current and charge balanced stimulation pulses. The control unit, consisting of a two-processor system including 16 analog inputs, has sufficient computing capabilities to generate simple stimulation patterns for muscle testing and strengthening as well as complex stimulation sequences or sophisticated control strategies. The stimulators can be adapted to central and peripheral paralysed handicapped. The battery powered devices are, depending on the mode of application, sufficient small and portable to allow the handicapped to carry the system with himself.

INTRODUCTION

Paralyzed patients starting the FES program have to undergo a certain procedure. For the different phases of the installation and the modes of application of FES appropriate stimulation devices have to be selected. Before starting with the FES first the testing of the remaining innervation and the muscular condition is necessary. During the installation of FES and the following training program the progress in strength and fatigue resistance has to be checked repetitively. In a last step the FES induced movements are adjusted to the handicapped. Because the requirements are changing according to these phases currently at each step stimulation systems with varying specifications have to be employed.In the last few years a line of stimulation systems meeting these requirements has been developed.

General Technical Requirements

All stimulators have to deliver rectangular constant current pulses with charge compensation. The latter can be provided by the discharge of a serial capacitor or a second current pulse in reversed direction.

The stimulation parameters should be adjustable independently at each channel. The pulsewidth has the range from 20 to 1000 μs and the pulse interval from 0.01 to 2 seconds. When using surface electrodes stimulus amplitudes up to 100 mA are required, and for percutaneous electrodes amplitudes up to 30 mA are sufficient.

Much more stimulation power is required for the treatment of peripheral paralysis. The pulsewidth has the range from 1 to 500 ms and amplitudes up to 100 mA. A precise control of the electrode-skin impedance is indispensable in order to avoid noxious current densities. If the impedance is to high adequate reactions according to the application have to be initiated, like switching off the stimulation current or ringing a signal. For safety reasons the devices are battery-powered.

The stimulation system must be simple. Handling with the device should be easy enough to allow home application by the handicapped as well as the therapists who have little, if any technical knowledge. For this reason the set of parameters presently used should be shown at a display. All the stimulation channels should be controllable independently.

SPECIALIZED STIMULATORS FOR EACH TASK

Testing the State of Innervation of Paralyzed Muscles

To execute the test routine at patients with peripheral and central lesions the stimulation pulses will be varied continuously in a large range. In this routine the relation of the pulsewidth being varied and the current amplitude required to reach the contraction threshold is recorded. The pulsewidth ranges from some microseconds up to 800 ms at a current amplitude up to 100 mA. The resolution of the amplitude is 1 mA and the one of the pulsewidth is 5 μs. To simplify the test routine the amplitude and pulsewidth, displayed simultaneously, can be changed continuously as well as in preset steps.

Testing of Electrode Sites and Stimulation Parameters, Training of strength

Small stimulators for testing with 2 or 4 channels, are used for positioning the electrodes and for the evaluation of appropriate stimulation parameters which permit a simple variation of the stimulation parameters, for example by potentiometers. Each output of the 4-channel stimulator can be equipped with a circuit for the generation of stimulation pulses (from 10 to 1000 μs), as well as with a circuit for the generation of pulses ranging from 1 to 150 ms, and of current amplitudes up to 100 mA. Therefore they may be applied to the treatment of peripheral as well as central paralyzed muscles.

These stimulators may also be used during the training procedure. For this reason they are equipped with a circuit which can switch on and off the stimulation channels in variable sequences and duty cycles with preset stimulation parameters.

In combinations with an autonomous Z80-microprocessor as a feed forward control unit these stimulators provide simple stimulation patterns composed by the combination of four channels being controlled by one switch only. In this way a quadriplegic is enabled to initiate entire movement patterns by a movement of the chin or those parts of the upper extremity that are still voluntarily controllable.

Testing of Muscle Strength and Fatigue Resistance.

During the entire stimulation program the investigation of the status of strength and fatigue resistance of the paralyzed muscles is very important. For this purpose we use a Z80-microprocessor based system [4] to calculate the maximal strength and the fatigue index in relation to the applied stimulation parameters. This system includes the signal processing of the measurement data and a one channel stimulator with stimulation parameters controllable in a wide range (I from 0 to 102 mA, pulsewidth from 10 to 128 ms, frequency form 0 to 50 pulses per second) with a sufficient resolution (0.4 mA for amplitude; 2 μs for pulses less than 512 μs, and 4 μs for pulses shorter than 1 ms, and 2 ms for pulses shorter than 128 ms). To monitor the torque at the hip, the knee and the ankle joint the handicapoped's leg is attached to a special device, transforming the all three torques simultaneously in a electrical signal by strain gauges. Various testing routines can be run automatically, controlled by the measurement system itself or by a personal computer. The data are sampled , stored and displayed as data or diagrams at the personal computer. The system may also be used for testing the site of innervation and excitability of paralyzed muscles.

To evaluate the muscular condition of a qaudriplegic's finger a measurement system has been developed, which enables the therapist to record the force of every finger and the thumb independently [8].

Training and FES of the Lower Extremities

For the daily routine in standing and walking by FES in combination with walking aids and for judging the handicapped's coordination while doing so, a program controlled open-loop 8-channel stimulators is used [2,3]. Although this device is based on a Z80-microprocessor it permits rather limited adjustment by the paralyzed while being in functional use. The stimulation is applied with preset pulsewidth and interpulse interval (50 to 500 μs and 2 to 40 pulses per second), only the pattern of the current amplitude (0 to 100 mA) is variable preprogrammable in a rather simple way. This way of generating movement patterns is for sure sufficient for the strengthening of the paralyzed muscles and for the execution of simple functions. Eight sensor inputs are provided if needed but the installation of closed-loop control is very limited due to performance of the Z80 processor. A version of this stimulator is commercially available with four or eight channels.

Working with these stimulation systems, the generation of stimulation patterns proved to be insufficient for stabilisation of the trunk in addition to the hip and knee joints. Therefore a 12 channel stimulation system was developed. The range of the stimulation parameters is the same as the one of the 8 channel stimulators. In addition to these features the possibility to generate pulses with stochastic pule intervals is installed in order to diminish the habituation of the withdrawal reflex used to lift the leg.

In this stimulator the structure of the control program has been changed completely to allow more sophisticated stimulation patterns. This program is similar to be applied in the daily routine. The enclosure with the power supply incorporated is 9 x 13 x 19 cm. The weight is about 1.2 kg.

FES of the Upper Extremities

FES of upper extremities requires the same specifications of the output stages but other control units. Therefore a 8-channel stimualtion system controlled by a Z80-processor was developed for the FES of patients with lesions of the upper spinal cord. The goal was to be able to handle the system by one switch only operated by any residual voluntary muscular function, like the chin. Four enlarged keys and a display at the front of the stimulator provide an easier control by the user. The power supply and the stimulus output stages are designed in such a way that both surface electrodes and percutaneous electrodes can be applied at the same time.

A further development of this device based on a single chip microprocessor (SAB 80C535 of Intel's 8051-family) is used for the investigation on sensors and closed-loop strategies. For this purpose it can be controlled only by a personal computer.

The housing of both devices, including the battery powered voltage supply, is 20 x 11 x 5 cm, the weight is about 1 kg.

Treatment of Spasticity

For the treatment of spasticity besides the common technical specifications of the stimulator the pulse frequency has to start at lower values and the coordination of the stimulation channels has to be less sophisticated. Thus a simple 8-channel stimulator with pulse frequencies ranging from 0.3..100 pules/second and the amplitude simple adjustable by potentiometers was developed. To provid a more comfortable handling the frequencies can be varied continuously as well as in preset steps. The enclosure has the same size as the 8-channel stimulator for upper extremities described above.

DEVELOPMENT OF A MODULAR STIMULATION SYSTEM

According to the experiences gained from the differnt stimulation systems described so far it became obvious that a single modular system [5,6] which could be easily adjusted to the different modes of applications would be much more operational. Besides the above described different applications this system should incorporate the ability to implement also extented controll strategies for the evaluation and the prospective daily use in FES.

Output Stages of the Stimulator

In this conception one has to distinguish between three output stages for different applications: stimulation of central paralyses with a). surface or b). percutaneous electrodes and stimulation of c). peripheral paralyses.

For the stimulation of **central paralyzed** muscles with surface or percutaneous electrodes the same principle to generate the stimulation pulses (Fig.1) may be used. One pulse including the charge compensation lasts at the most 4 ms, one voltage controlled current source, driven by a unipolar 200 V supply voltage, is sufficient to operate 8 channels at frequencies up to 32 pulses/sec. The stimulation pulses generated by one source are distributed to the different electrodes by pairs of relays. This concept permits besides the normal operation a round-about stimulation by combining different pairs of electrodes. By using this principle a galvanic isolation of the stimulation channels is not required. The circuit is space-saving and needs only low power. To balance the applied charge a capacitor is connected in serial to each pair of electrodes, which is charged during the anodic stimulation phase and discharged in the cathotic phase through the tissue. The current source provides for surface electrodes up to 100 mA at electrode-skin impedances up to 1.5 k. Using percutaneous electrodes a stimulation current up to 30 mA is sufficient.

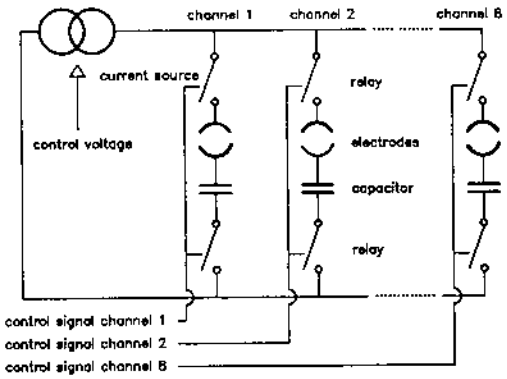

Fig. 1: Generation of short stimulation pulses (0.5 ms) at 8 channles using only one current source

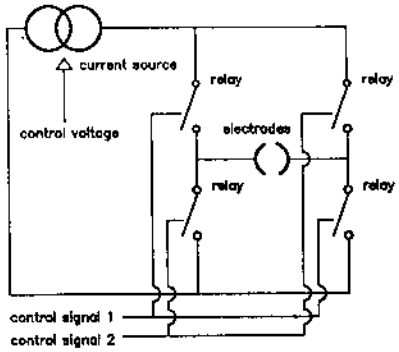

Fig. 2: Generation of long stimulation pulses

For safety reasons the supply voltage is reduced to 40 V in this case. Applying surface electrodes and percutaneous electrodes at the same time, the supply voltage can be switched from 200 to 40 V by a relay at every stimulation pulse .

The treatment of **peripheral paralyses** requires pulses with a duration longer than 1 ms. For different reasons it is impossible to operate the channels in a muliplexed mode in this case. Therefore each channel requires an independent current source with an isolated supply voltage of about 150 V to get amplitudes up to 100 mA at an impedance of 1.5 k. In this case the load compensation is ensured by a current pulse of the same amplitude and pulsewidth but the electrodes being reversed by a pair of relays to reverse the direction of current flow (Fig.2). To reduce the large power consumption the supply voltage is adjusted continuously to the actual stimulation current. During every pulse interval the supply voltage is switched off.

Control Unit

Recent research showed that paraplegics using an 8-channel stimulator are limited to stand up and walk in a very basic way. The application of more stimulation channels can refine the FES induced movement by stimulating more muscles and generating a better stabilisation while walking by controlling actively more of the paralysed joints.

To operate more stimualtion channels a two-processor control unit was developed due to the limited performance of the Z80-system. This unit (Fig. 3) consists of two micorprocessors, the stimulation processor and the communication processor, connected by a dual-ported RAM.

The stimulation processor runs the output stage by taking the actual stimulation parameters, calculated by the communication processor, from the the dual ported memory and generating the control signals required by the output stage. These signals are used to switch on and off the stimulation and the compensation pulse by means of the relays and to adapt the current amplitude by a 8-bit D/A-converter. This part of the control unit consist of a Z80-CPU (4 MHz) and a 32 kB program memory , a 8 kB data memory and 2 kB dual ported memory. For delivering the control signals parallel ports, timer/counter and a multiple channel 8-bit D/A-converter are used.

The assignment of the communication processor is the interaction between the user and the entire stimulation system and the timing of the stimulation course. Therefore the stimulator is equipped with a liquid crystal display, a keyboard, several timer/counters, parallel, and serial ports to transfer data between the personal computer and the stimulation system.

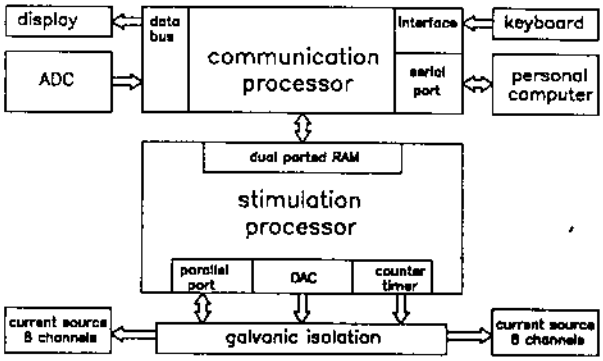

Fig. 3: Block diagramm of the entire stimulation system

The communication processor is installed in two different versions. For the open-loop of of movements a Z80-CPU with both 32 kB program- and data memory is sufficient. In combination with the output stages operating 16 channles for FES of central paralysis it can be employed in the evaluation of new coordination schemes and in the daily routine in standing and walking. The reasonable small enclosure (22 x 22 x 7 cm) enables the handicapped to carry the device with himself when walking crutch supported.

To treat peripheral paralyzed patients the control unit is combined with four single channel output stages which provide pulses longer than 1 ms. Because of the

larger battery capacity needed the enclosure is 22 x 22 x 14 cm. The weight is about 2 kg.

A MC68000-processor (10 MHz) is employed for complex movement patterns and for the implementation and evaluation of closed-loop control strategies. This unit has a 192 kB prgram and a 128 kB data memory. To allow a comfortable testing it is possible to transfer control strategies implemented in a high-level language at a personal computer to the stimulation system.

In both versions of the communication processors 16 analog and digital input lines can be used for connecting sensors directly.

Generation of Complex Preprogrammed Stimulation Patterns

The generation of the stimulation courses is realized as an open-loop program control consisting of up to 30 different movement patterns. The course of each pattern is divided into two different modes of operation: during the *halt-mode* (marked by [...]), like *standing* and *sitting*, all stimulation parameters are kept unchanged. Starting from such a halt period a *movement-mode* (marked by {...}) like *standing-up*, *walking* or *climbing stairs*, can be initialized by switches attached to the walking aids or to the stimulator. At the end of every movement pattern the user automatically is in the halt-mode. Furthermore the user is able to interlink these movement patterns, for example: [*sitting*] - {*standing-up*} - [*standing*] - {*lift of right leg*} - [*standing*] - {*lift of left leg*} - [*standing*] - {*sitting down*} - [*sitting*].

Every movement mode is subdivided in several segments, which are characterized by their starting- and their final values, so called 'fixed points'. This set of values consists of the stimulus amplitude, pulsewidth and pulse interval. While stimulating the parameters are interpolated between the starting and the final point of the segments and stored into the dual ported memory. Out of these data the stimulation processor generates the stimulation pulse.

Every movement mode consists of 33 aequidistant points. 16 of them can be defined as fixed points by declaration of their starting point. To adjust the length of a movement phase to the paraplegic's requirements the distances between these fixed points may be set from 64 ms to 6.72 sec in steps of 2 ms. The very complex adjustment of the movement patterns is done graphically on a portable personal computer. The 15 kbyte data are then transferred in serial to the stimulator. Programing the stimulator via its own keyboard is also possible. But it is very inconvenient because the the stimulator has only few keys and a limited capacity of the display.

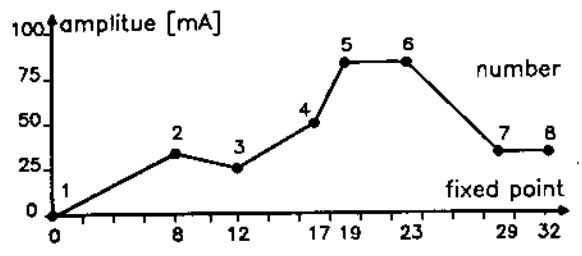

Fig. 4: Diagramm of a stimulation pattern

CONCLUSION

With these stimulation systems a very variable tool to handle the different tasks in the treatment of paralyses has been developed. Because of its relative small size and little weight - especially of the 12 channel stimulator - these devices can be used during the installation of FES as well as in the daily routine at home. The performance of the MC68000 enables the 16-channel stimulation system to assist the evaluating of new open-loop as well as closed-loop control stragies in a very easy and operational manner.

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