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# DEVELOPMENT OF AN EMG-CONTROLLED 8-CHANNEL SYSTEM FOR NEUROMUSCULAR FUNCTIONAL STIMULATION

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ABSTRACT

Control signals of technical systems for Functional Electrical Stimulation (FES) have ultimately to be submitted to the patient's discretion. Experience shows that this is very difficult and in many cases even impossible, since simple limb movements already require complex patterns of agonistic and antagonistic neuromuscular activity. Although physiological innervation patterns can be simulated by highly sophisticated microprocessor devices in conjunction with position/force-sensors to a variable extent, the problem for the patient remains of learning complex sequences of motions or innervation patterns of simulated movements by healthy muscular units, which primarily serve quite different functions.
Depending on the origin and the degree of the palsy, i.e. the neuromuscular lesion, there are cases that the physiological motoric system still is in the position to transmit reduced innervation signals to the original muscles, thus provoking a limb movement or an isometric contraction at least to a limited degree. However, the sum of the physiologically induced actionpotentials within the muscular region is not sufficient to perform forceful limb actions.
Accepting these facts it seemed promising to develop a technical rehabilitation aid which, after having sensed and transmitted the residual actionpotentials in circumscribed muscular regions, evaluates and amplifies the transmitted signals externally and feeds them back into the same region for artificial muscle stimulation by means of implanted Miniature Electro-Stimulators. These then would stimulate the residual, resting motor units, thus provoking sufficiently strong muscle contractions. Physiologic prerequisite is naturally that the bulk of the muscle has not atrophied yet. This in turn, can be provided quite readily with help of already known percutaneous electro-therapeutic methods.
Since a smooth and controlled limb movement requires differentiated and independently modulated muscular contractions in a variable number of muscular regions, technical postulate is the availability of a MULTI-CHANNEL SYSTEM OF IMPLANTABLE EMG-SENSORS AND CORRELATED ELECTRO-STIMULATORS INCLUDING EXTERNAL EMG-DATA HANDLING, AMPLIFYING AND TRANSMITTING DEVICES.

## DEVELOPMENT OF THE SYSTEM

Serving the above described purpose, in summary, the development and investigation of the following system was achieved:

1. Implantable (wireless), multi-channel Miniature-Telemetric EMG-Sensors.
2. Receiver with data handling and amplifying unit for receiving, decoding, rating, and amplification of the EMG-signals incl. receiver antenna.
3. Transmitter with address and stimulation-pulse coding-unit for consecutive or random addressability and energy supply for the implanted Electro-Stimulators, incl. sender antenna.
4. Implantable (wireless), multi-channel Miniature Electro-Stimulators for Functional Electric Stimulation (FES).

In Fig.1 a model of such a system in application to a case of neural lesion is sketched. Here an affection of the spinal ganglion is assumed at which for instance one motor-unit is still intact (black triangle, full line and 3 black dots), whereas the other motor-units as result of the damaged neurons cannot be physiologically activated. An actionpotential telemetric sensor measures the residual activity by its electrodes within the muscle itself or close to the region to be artificially activated. The residual AP is amplified and transmitted to an external AP-receiver. Here the proportional signal is being decoded, amplified, rated, recoded and transferred to an external transmitter. This sender transmits the signal in coded form to a stimulator, which is located within the muscular region to be stimulated, setting the stimulation-pulse intensity, frequency and duration as function of the measured residual AP-(EMG-)signal. This stimulus is made sufficiently high to stimulate the resting denervated motor-units thus generating a forceful contraction of the parethic muscle.
In Fig.2 the correlation between the AP-signal and the amplitude of the stimulation-pulse is depicted for one channel. It can be seen that by the transmitted analog signals of the compound-actionpotentials a proportional DC-signal is being generated in the receiver, which in turn is modulating a high-frequency carrier (27,12 MHz) with a special five-bit code, this being transmitted to the respective stimulator.
Since a smooth movement of a muscular functional unit, as opposed to a tetanic one, only can be achieved by differentiated supramaximum stimulation of bulks of synergistically activated muscular aggregates, it is necessary to have a higher number of telemetric sensors and corresponding stimulators, which can be put to work separately and sequentially according to the input-signals of their correlated AP-sensors. For this reason, a multichannel system - Fig.3 - has been developed. On the left 8 implantable telemetric sensors with defined and discrete frequencies and 8 implantable stimulators, which alternately or successively can be addressed by the telemetric sensors, are shown.
At the right hand side of the picture, materially separated by the skin, the external receiver, transmitter, coding and decoding units, multiplexer, signal amplifying and rating electronics incl. receiving as well as sender antenna are to be seen. By operating the system in multiplex-mode, all channels can be activated within a fraction of the period of the stimulation frequency. This is made possible by a frequency code of the AP-sensors, which is correlated to the pulse code of the addressable stimulators. This five-bit code serves two purposes, first the selection of the stimulator to be activated, and secondly the generation of the required stimulation-pulse intensity as function of the sensed compound-actionpotential. Each stimulator is being addressed and controlled twice per period of stimulation frequency by means of this code word. The first sender signal triggers firing of the stimulator, which is automatically followed by the recharging process of the energy-capacitor, and the second signal terminates this recharging process. It should be mentioned here that the energy supply for the AP-transmitter as well as for the stimulator logic and for the generation of the stimulation energy as such is being furnished by the external transmitter via the 27,12 MHz-carrier. Another quite important detail, the so-called echo-barrier, shall be just briefly mentioned here. This feature

provides blocking of the AP-sensing process while the stimulator is firing and during the charge-off command. This way, reliable artefact suppression is being accomplished.
The implantable 8-channel stimulator consists essentially of the logic part containing the channel-code electronics and of an analog part for the generation of the stimulation-pulses. The logic, which is based on the afore-mentioned five-bit code, is in essence integrated on a customized mono-chip (ca. 3 x 3 qmm). The pulse generator comprises the storage-capacitor, which is being charged by a constant current source in pulse-duration mode controlled by the proportional values of the AP-signal.

The next picture - Fig.4 - shows the five-bit code, the functions of which has been described in former publications (2,3,4). As can be seen from Fig.5, the negative stimulation-pulse has an exponential decay as is typical for a capacitor discharge. Its amplitude is dependent on the variable charge-duration tL(var), which in turn is a proportional function of the transmitted AP-signal. The half-width of the stimulation-pulse is approx. .5 ms and thus safely exceeds the 'chronaxie'-time.
For obvious reasons it is not feasible to point out here in detail the rather complex correlations for generating AP-controlled stimulation patterns within the total system. However, Fig.6 shall give a brief indication of the PCM-sender signals and the corresponding stimulator responses for 4 channels. The vertical bars in the upper row represent the amplitude modulated PCM-sender signals which at higher resolution are to be recognized as the five-bit code words. The abscissa shows the time scale for roughly 1 1/2 periods of the given stimulation frequency of 50 Hz. The sections, stimulator 1 to stimulator 7, beneath the time axis describe the charging and discharging (firing) functions of the respective stimulators. It is readily to be seen that the 'start'/'stop'-signals can be packed that means that the stimulators can be addressed randomly during one period of the stimulation frequency.

## EVALUATION OF THE SYSTEM

Fig.7 gives a schematic example for the correlation of the EMG-sensor signals, the PCM-transmitter signals and the stimulation-pulses as function of the measured EMG-signals for 2 channels, A and B. It can be derived from these diagrams that the envelopes of the negative stimulation-pulses resemble in fair approximation the original envelope of the stimulation-generating myosignals.
The following oscilloscope pictures Fig.8 and Fig.9 in fact prove these expectations. Thus shows Fig.8 increasing stimulation (lower trace) with increasing voluntary innervation (force) in palmar-flexion of the hand (upper trace) with a time resolution of 10 ms. The faint dots just below the middle line of the diagrams are the 'start'/'stop'-signals generated by the external transmitter correlated to the compound-actionpotential signals. Fig.9 finally shows the relation between the AP-signals, the intensity of the stimulation-pulses and the duration of the pulse-trains as well as the integrated DC-signals, which are being formed in the external data-handling unit in consequence of the received EMG-signals. The upper oscillogram shows one burst of the AP-signals of approx. .4 s duration, whereas the lower oscillogram is exhibiting a sequence of 3 voluntary force-

ful palmar-flexions of the hand, each lasting approx. 200 ms. Here again the stimulation pulse-trains resemble quite well the physiologically induced muscular activity with a gain of at least 10 to 20.

## SYSTEM HARDWARE

Fig.10 shows a laboratory proto-type of the AP-transmitter/sensor (EMG-transponder) which was being fabricated in conventional technology, that means with micro-components soldered under the microscope. Among others it contains two antennas, one for receiving the high-frequency carrier of 27,12 MHz for the power-supply and one sender antenna for transmitting the EMG-value, sensed within the particular muscular region, within the frequency range of 40,68 to 40,75 MHz. This AP-transponder exhibits two Ti-electrodes being in contact with the muscular tissue and is hermetically sealed in a small cylindrical capsule made of biocompatible ceramics (Fig.11).
The addressable and programmable 8-channel stimulator is depicted in Fig.12. The left hand side shows the antenna for receiving the energy for power-supply as well as for the coded informations with the pertaining components, whereas on the right hand side essentially the digital elements are to be seen, especially the relatively large mono-chip, which serves the internal fixation of the channel code-number. Both circuits are built upon aluminum oxide ceramics and connected to the etched gold lines by ultrasonic bonding. The whole hybridized array is being sealed into the same biocompatible ceramics housing as the EMG-sensor/transmitter. The two Ti-electrode pins are sintered into the ceramics housing by special processes (4). In Fig.13 an address-coded programmable stimulator is shown ready for use. The next picture (Fig.14) depicts the complete actionpotential-controlled stimulation-system comprising the AP-transponder, address-coded programmable stimulator, the external receiving data handling, and transmitter electronics incl. the receiver- and transmitter-antenna as well as the main power-supply (batteries). The total system is, as can be seen, mounted on a leather belt which can be worn by the patient in a normal way. The antennas, of course, can be shaped differently according to the special needs of the patient. Thin coaxial cables can readily be fixed to inner parts of the patient's clothing.

## FIRST CLINICAL TEST

In order to prove the function and the biocompatibility of the implants (EMG-transducer,stimulator) and to test the operative handling as well as the question of 'cross-talk' of the different channels, a first clinical trial was carried out. Three differently address-coded stimulators were implanted in the quadriceps-group (M.M. vastus lateralis, vastus medialis, rectus femoris) of a patient, with knee extensor muscles, highly atrophied by a former neurogenic lesion. Although this is not being considered to be a typical application, above all, for the reason of almost complete muscle atrophy, the results were very favourable insofar as it was demonstrated that the implantation and the correct location could readily be done under local anesthesia by testing the most effective location by 'in situ' stimulating with a sterilized antenna.
Prior to the operation the stimulators were put into transparent bags (Fig.15) for usual gas sterilisation. Before sealing of the

envelopes, small cylindrical LED-devices were clipped onto the electrodes. These visual indicators serve the purpose of functional testing after the sterilisation process prior to the implantation. They are easily to be detached intra-operatively and can be reused many times. Fig.16 shows an x-ray picture of the three implanted stimulators. As result can be stated that sub- and supra-maximum stimulation in the full frequency range from 10 to 50 Hz could be achieved for prolonged times and that maximum muscle contraction was obtained far below the pain treshold. There was clear and distinct channel separation (no cross-talk) and after explantation (approx. 3 months p.o.) only slight scar tissue formation close to the electrodes could be observed. During the whole time of implantation the stimulators stayed firmly in place. Only few days after the implantation a sort of foreign-body feeling had to be tolerated. After that time no further perception of the stimulators could be experienced at all.

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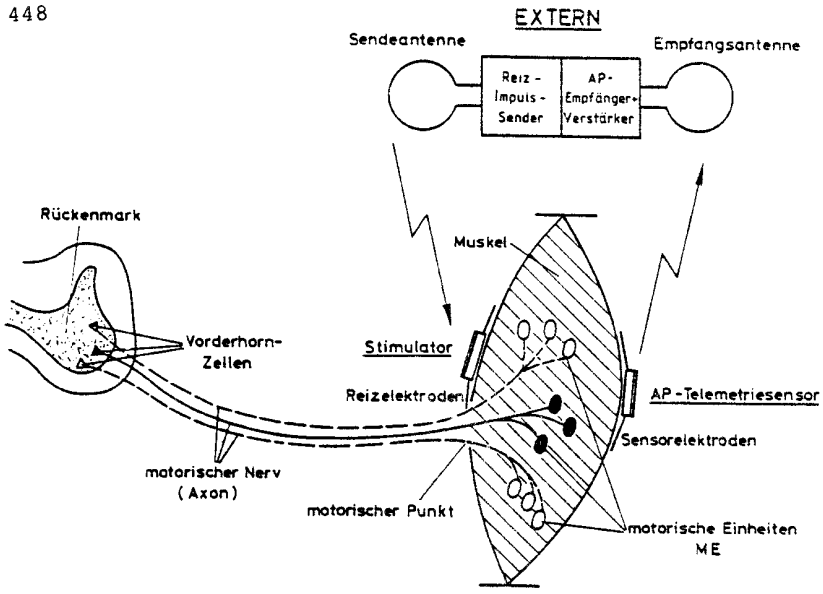



Fig.1 Principle Model of the AP-controlled Muscle-Stimulator

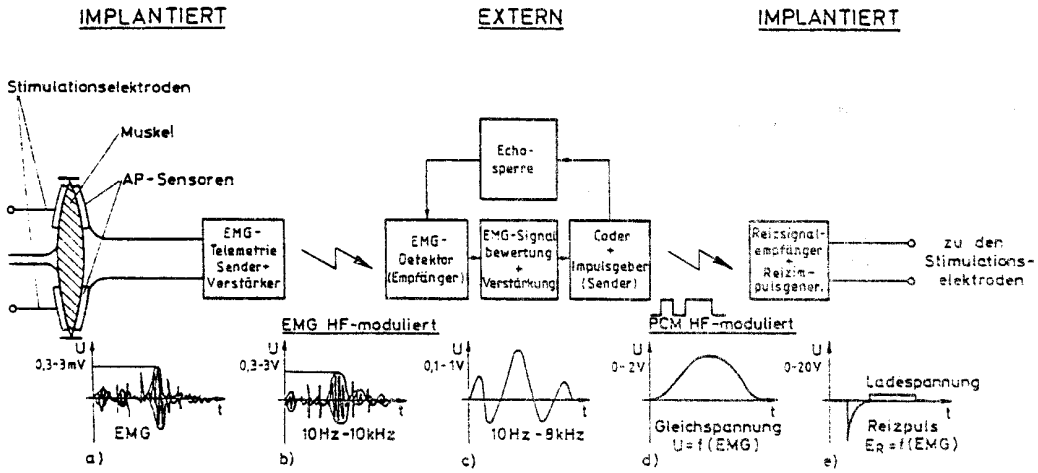



Fig.2 Function Scheme of the APC-Stimulator (one Channel)

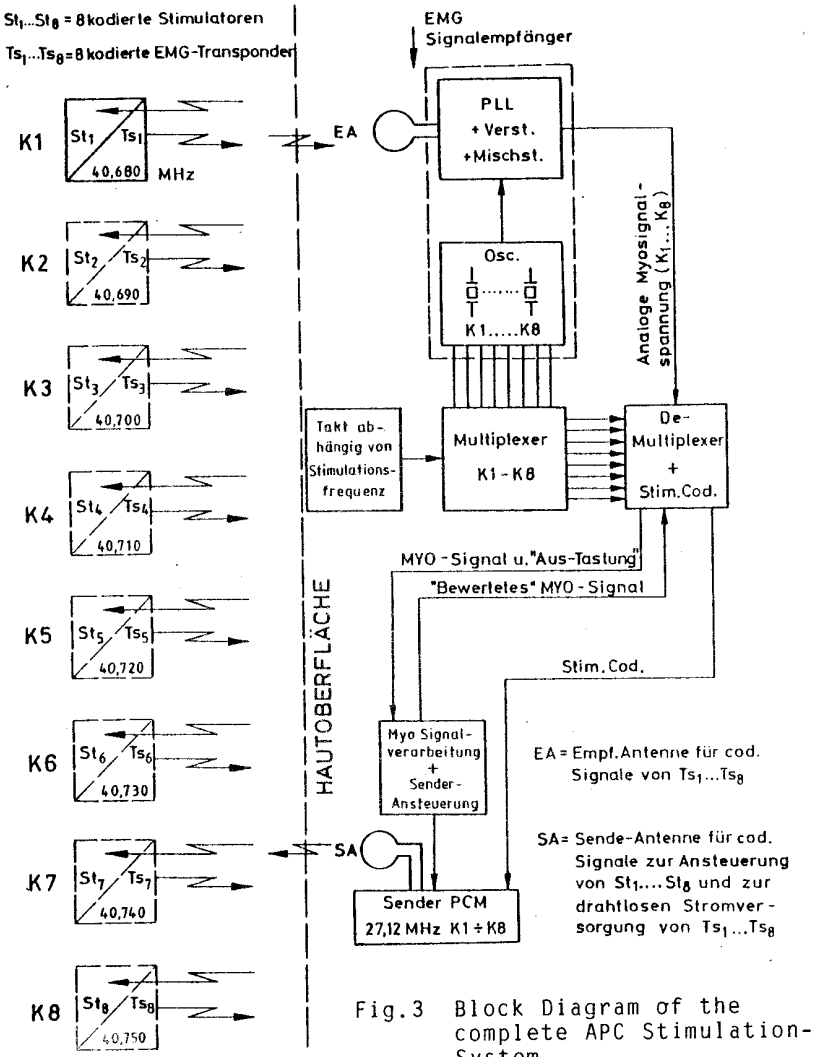



Fig.3 Block Diagram of the complete APC Stimulation-System

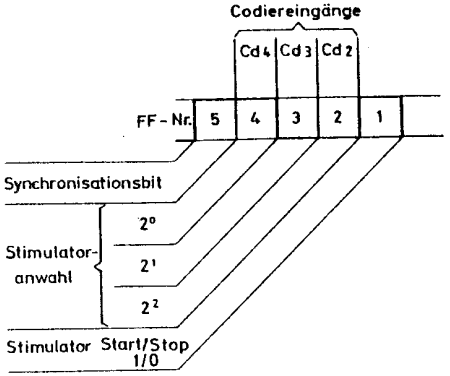



Fig. 4 Addressing & programming Code

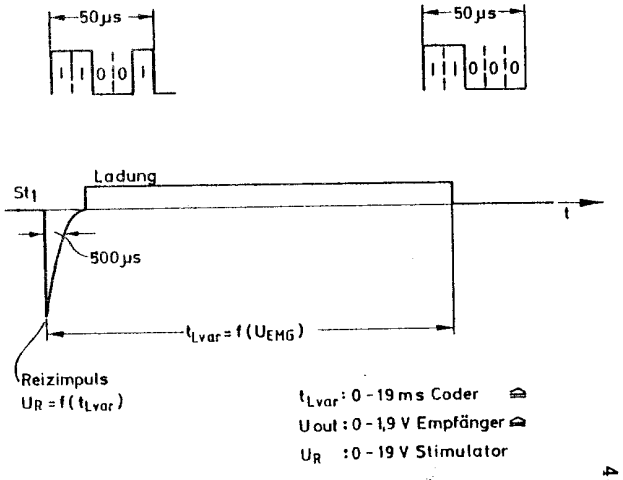



Fig.5 Control of Stimulation Intensity by the EMG

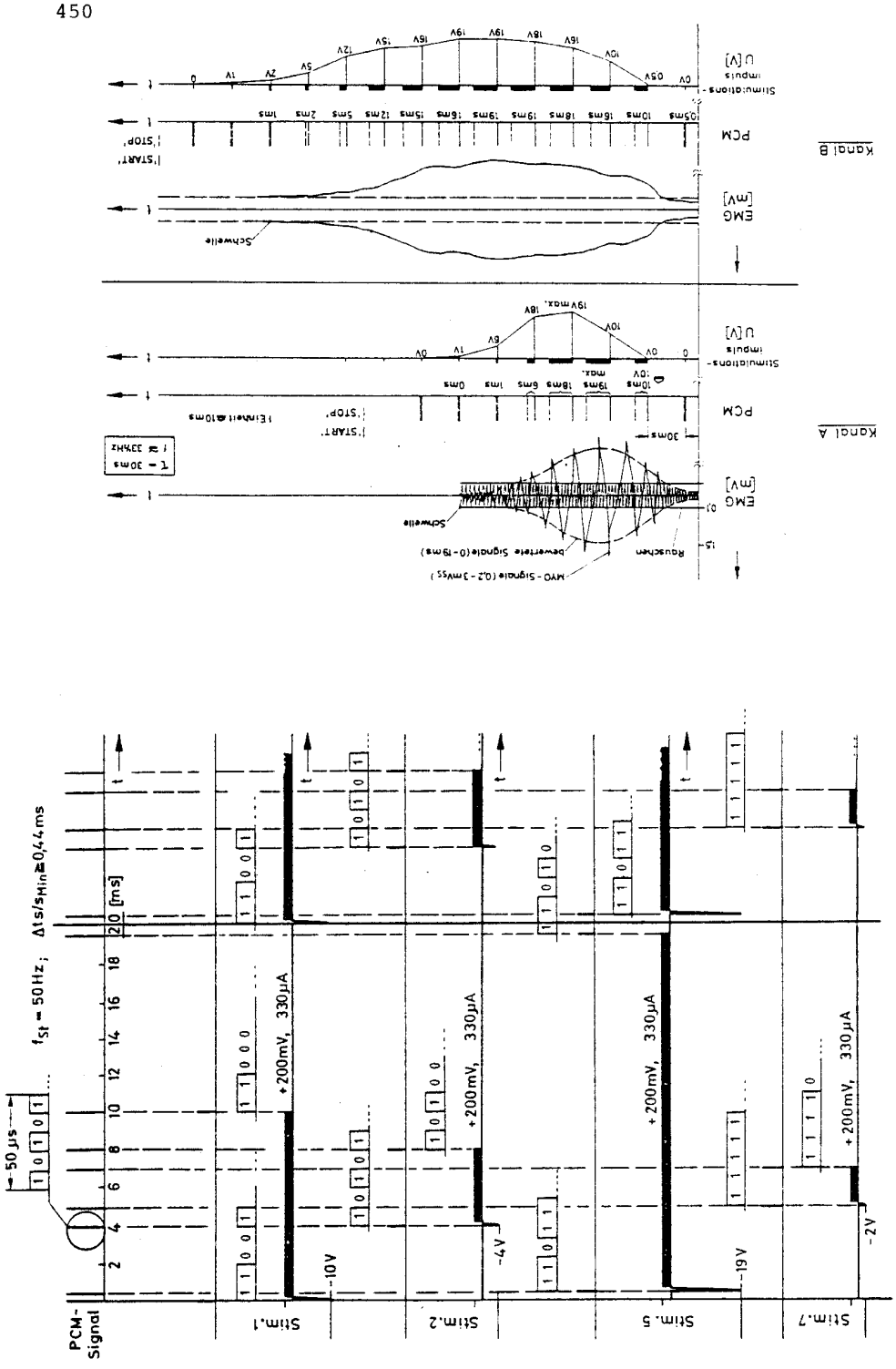
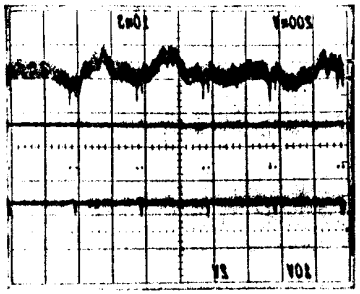



Fig.6 PCM Sender-Signals and Stimulator Responses (Example: 4 Channels)




Fig.7 CAPs, PCM Transmitter-Signals and corresponding Stimulation-Pulses (Example: 2 Channels)

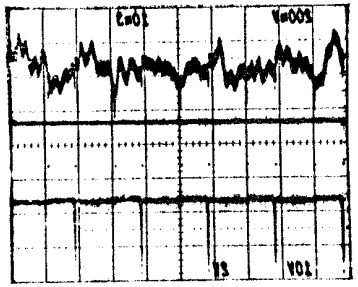


Slight Innervation

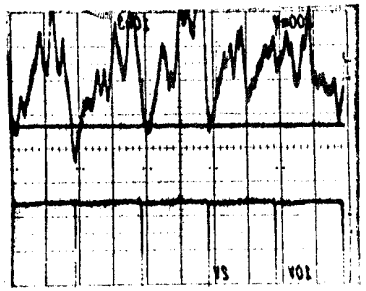
EMG

Start/Stop-Signals

Stimulation-Pulses

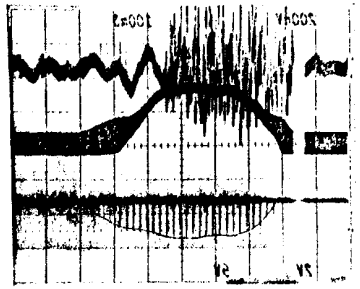


Medium Innervation

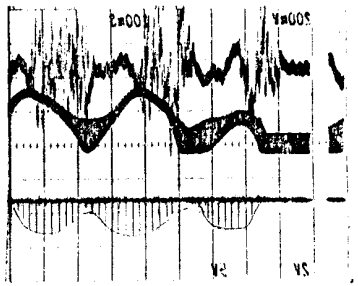


Strong Innervation

Fig.8 Voluntary EMG-Activity (Palmar Flexion) and evoked Stimulator Responses



One Hand Flexion



Three consecutive Hand Flexions

Fig.9 Integrated EMG-Activities with Palmar Flexion of the Hand, rated Signals and correlated Stimulation-Pulse Patterns

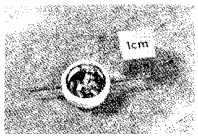



Fig.10
AP-Sensor/
Transmitter
(opened)

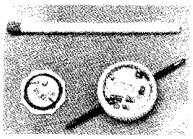


Fig.12
8-Channel-
Stimulator
(opened)

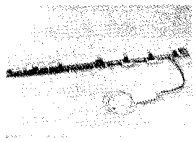


Fig.14
Complete APCS-
System

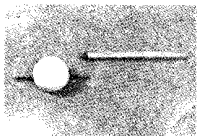


Fig.11
AP-Transponder
(sealed)

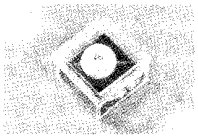


Fig.13
Address-coded
Stimulator
(ready for use)

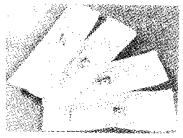


Fig.15
Four coded
programmable
Stimulators
(sterilized)

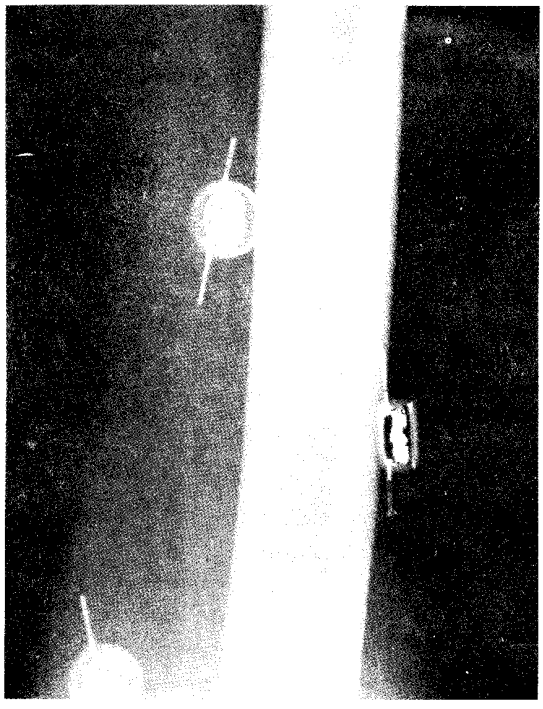


Fig.16 X-ray Picture of three distinctly coded 8-Channel Stimulators implanted within the Extensor-Muscles of the Knee