NEUROMUSCULAR FUNCTIONAL STIMULATION BY MINIATURIZED IMPLANTABLE ELECTRIC STIMULATORS.

PART III: DESIGN AND FABRICATION OF PROGRAMMABLE 8-CHANNEL DEVICES*)

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In the following a brief revision of the design principles of the previous development is given.

1. Revision of Design Principles

The basic requirements for implantable stimulation devices ought to be:

ease of implantation

minimum size

selctive operation

wireless operation for least risk of infection and mechanical damage

no internal energy source for obvious reasons.

In consideration of the state of the art the following operation parameters were accepted:

stimulation amplitude	$U_{St} \le 20$ V
stimulation frequency	10 Hz $\le f_{St} \le 50$ Hz
stimulation pulse-current	I_{St}
stimulation pulse-duration	100 µs $\le t_{St} \le$
distance transmitter-stimulator	$d_{St} \le 8$ cm

1.1 One-Channel Stimulator / 1 /

First hardware realizations of the one-channel miniature-stimulators resulted in two laboratory and animal-test prototypes (Fig. 1).

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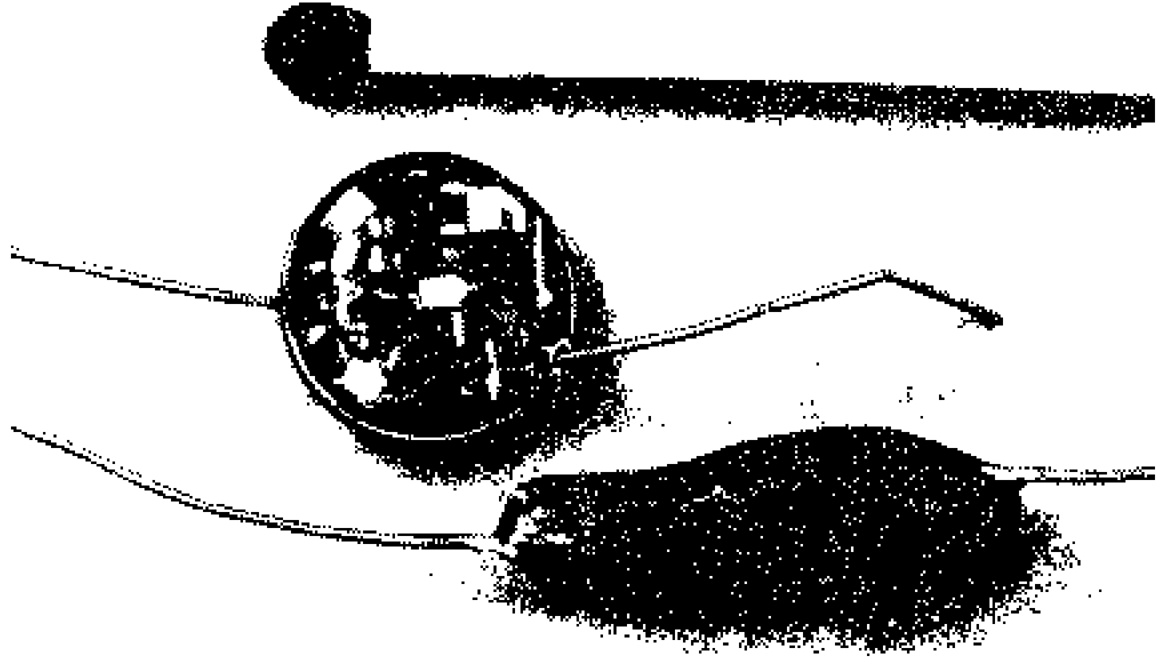


Fig. 1 Implantable Stimulator 'IS'
(One-Channel)
Experimental Models

A disc-like finish of ca. 10 mm diameter and a cylindrically shaped receiver of ca. 16 mm length and of ca. 5 mm in diameter were built. These stimulators generating pulses with fixed amplitudes were externally powered and triggered by an HF-transmitter, with an output of 3 W.

1.2 Programmable One-Channel Stimulator / 2 /

To give the opportunity to control the stimulus-amplitude externally an advanced design was developed. The storage capacitor is being charged during the stimulation pause for a preselected time by a constant-current source, thereby enabling an external control of the capacitor-voltage, which is equal to the required stimulus amplitude.

Figure 2 shows a completed programmable stimulator, ready for implantation.

The stimulation-pulse, of these devices are triggered by a short interruption of the HF-signal, thus generating a negative peak of up to -20 V and of ca. 0.5 ms duration. Figure 3 shows the time function of the complete process for one cycle. It can be recognized, that the discharge is followed by a time-variable charging interval determining the effective amplitude. While discharging as well as during charging of the stimulator's capacitor, the current flows through the tissues surrounding the electrodes. By this method, polarization effects can substantially be counteracted.

Figure 4 shows the one-channel system as it was utilized for the animal experiments.

After successful animal testing of the one-channel device, the next step was the development of an eight-channel system.

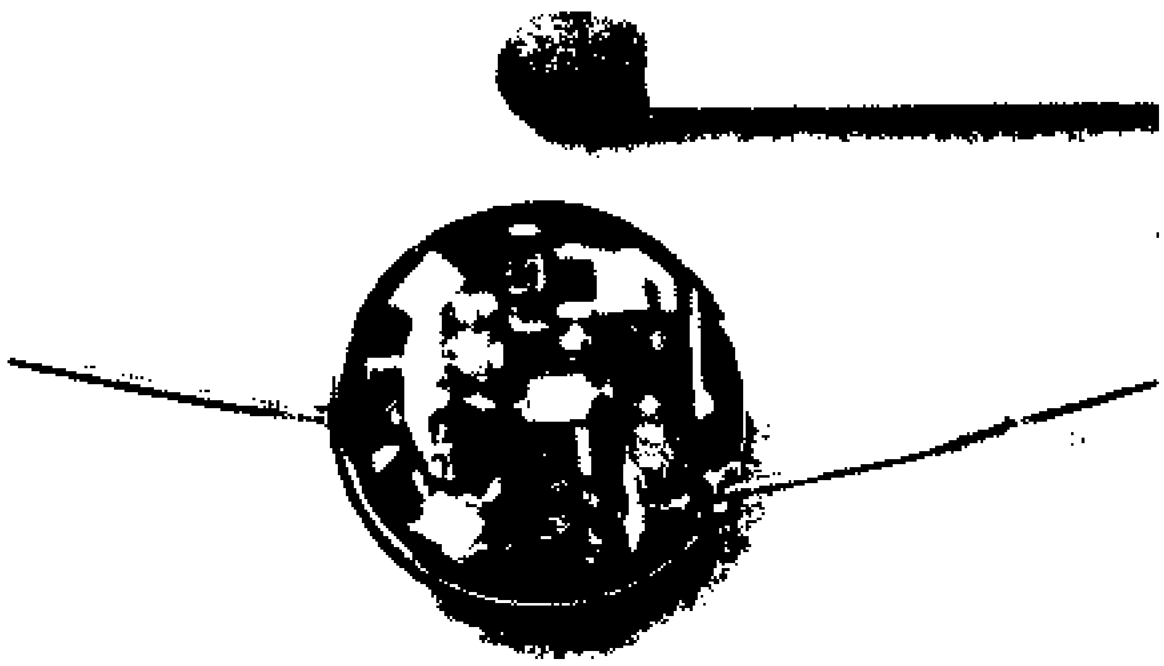
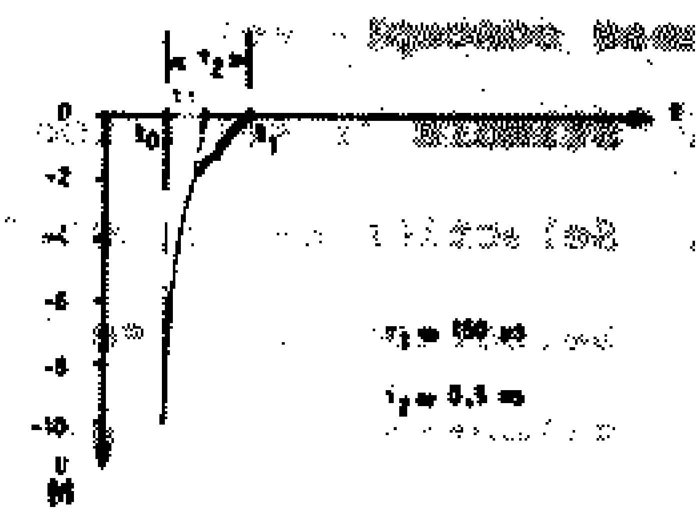
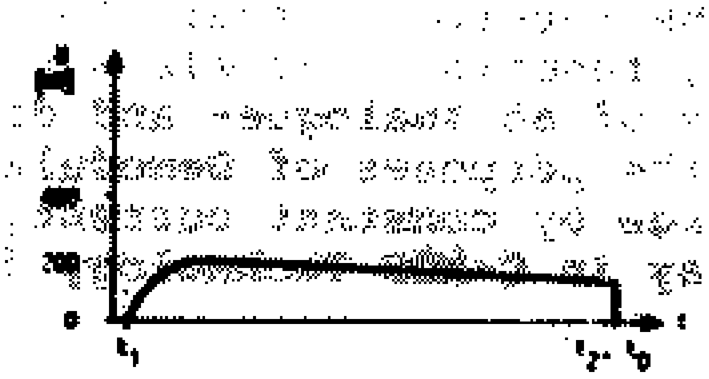


Fig. 2 Programmable Stimulator 'PIS' (One-Channel)



a) Stimulator Discharging



b) Internal Stimulator-charging function

Fig. 3 Stimulation-Pulse Time Function for one Cycle

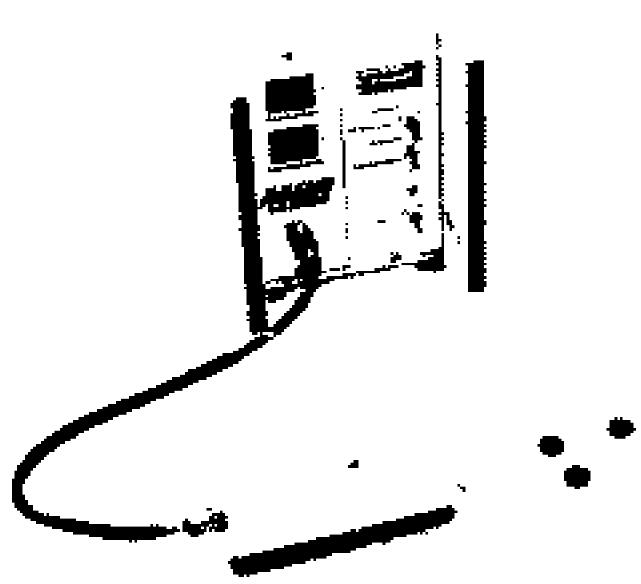


Fig. 4 One-Channel Transmitter with Programmable Stimulators

2. Design of Eight-Channel Stimulator

For the application of a multiple stimulation system the amplitude as well as the precise point in time of the stimulation pulses of each stimulator has to be set and controlled separately by the external transmitter. For this reason the signals are to be transmitted in a coded form and then must be decoded by the addressed stimulator.

There are several basic possibilities to accomplish this Four of them were evaluated in detail and their usefulness with respect to max. possible number of channels, their component consumption on the side of the receiver as well as the sender, the required technology and production cost was investigated. For each concept lab models were built and tested.

These concepts were:

a. Stimulator selection by various carrier-frequencies

b. Selection by sinusoidal Amplitude-Modulation (AM)

c. Selection by Pulse-Duration Modulation (PDM)

d. Selection by Pulse-Code Modulation (PCM)

Optimizing the criteria mentioned above, we decided on utilizing PCM.

The receiver circuit for the 8-channel PCM-System was developed, functional models were built and tested. The whole array consists of an analogue- and digital part. The analogue circuit serves the purposes of Demodulation, Voltage regulation, Capacitor charge by constant current, and pulse generation. The digital sub-array in C-MOS Technology decodes the transmitted information.

2.1 Signal Coding and Decoding

Following in brief the function of the stimulator-receiver: The receiver resonance circuit receives a 20 % amplitude-modulated signal which is being rectified and serves as power supply, and simultaneously by a dynamic demodulation circuit the amplitude modulation is gained as information signal.

This information is made up of a 5-bit code word, the first bit of which causes synchronization of the logic components of the decoding circuit (Fig. 5).

The following three bits are for stimulator-identification and selection, the last bit triggers the stimulation pulse and the following capacitor recharge. A zero-bit following the synchronization- and the identification bits terminates the recharging process and so defines the amplitude of the next stimulus.

This serial bit-sequence is red into a shift register, consisting of 5 Flip-Flops initiated by the start-pulse of the synchronization bit. Five shifts later the code-word appears in parallel at the register output. It then is compared to a fixed preprogrammed code, which is different and characteristic for each stimulator. If both patterns are identical the output-Flip-Flop of the respective receiver switches to 'on' or 'off' depending on the one- or zero-level of the last bit.

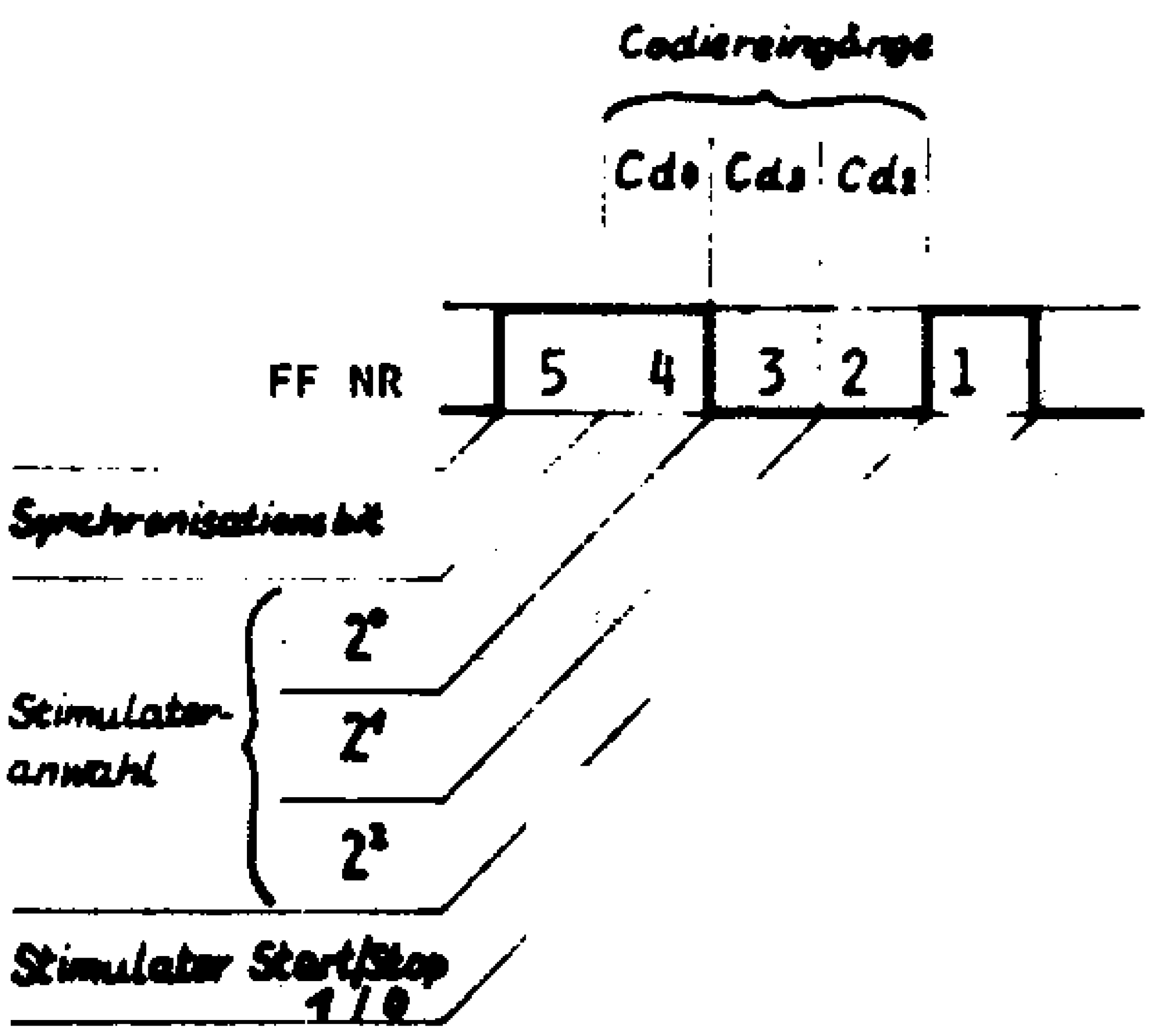


Fig. 5 5-Bit-Code

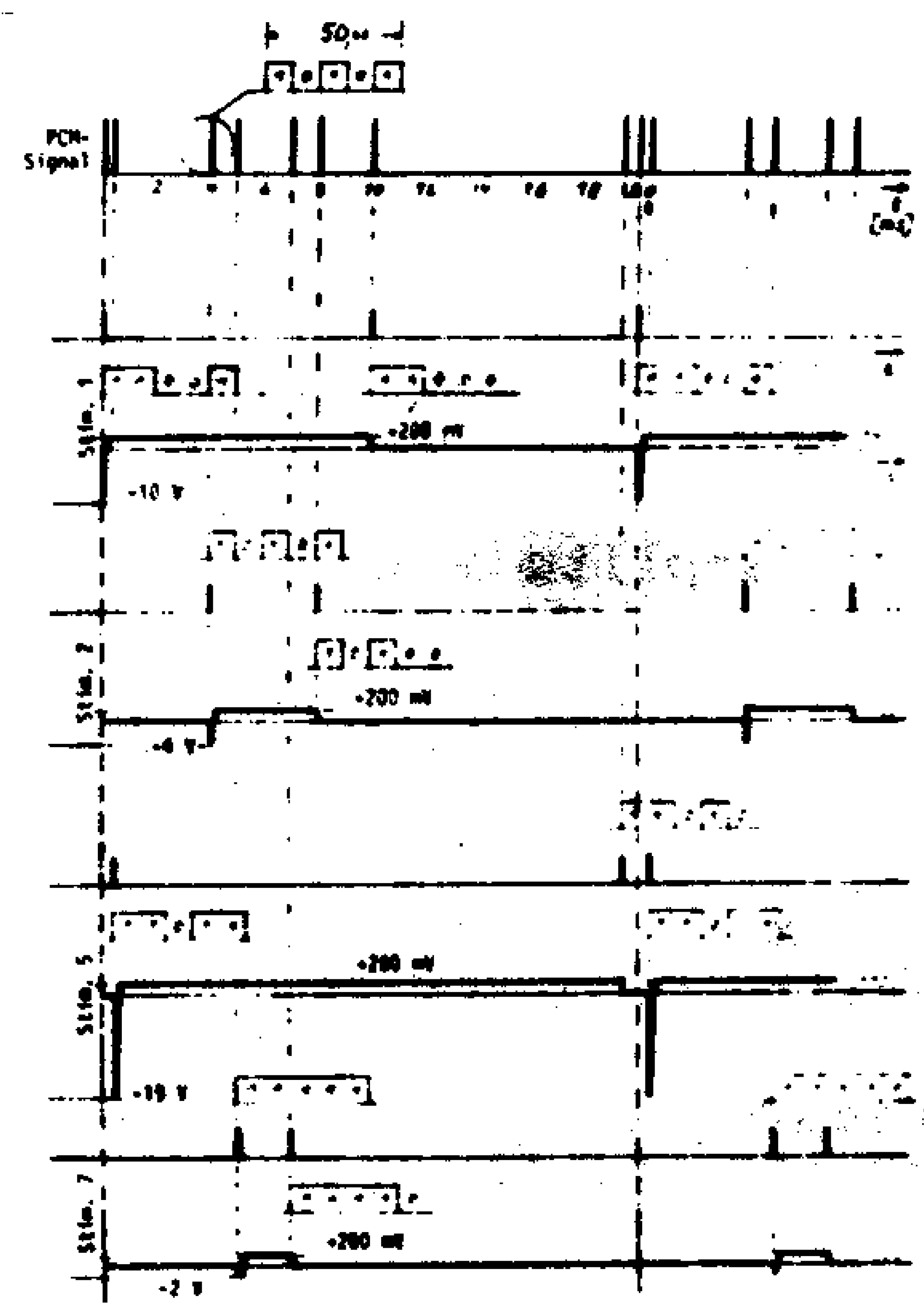


Fig. 6 PCM Sender-Signals and Stimulator Responses (Example: 4 Channels)

Figure 6 shows an example for the correlation of PCM-sender signals and stimulator responses for 4 serially addressed stimulators. Stimulating frequency is here 50 Hz (1/f = 20 ms). The time relation of the various channels as well as the respective amplitude are randomly chosen.

The PCM-signal, on an expanded scale to the recognized as the 5-bit word depicted previously, which is the 20● % modulation of the 27.12 MHz carrier, has a duration of 50 µsec. It is received by each stimulator and there specifically decoded as shown.

Since the energy-storage capacitor within each stimulator is charged by a constant-current source as mentioned previously a constant voltage of about 200 mv across the electrodes during the recharging time is to be seen in Fig. 6. This voltage of course depends on the value of the tissue resistance.

The information transfer-time of a 5-bit word is approx. 50 µsec. With a 20 msec. stimulation pulse-cycle this time-lag is negligible. Since only serial transfer is feasible, it takes 8 x 50 µsec. if all 8 stimulators are to be fired. For the charge-stop pulses another 400 µsec. are needed resulting in a total transfer-time of 800 μsec. This time again is very short compared to the minimum cycle time of 20 msec.

2.2 Eight Channel System

The power-/control-devices consist of three main components:

a. HF-Generator including power output

b. Antenna-Array

c. Coding-Module

A 27.12-MHz-Quartz oscillator is generating a stable HF-signal. The signal goes to a preamplifier and from there to an output module which provides the power amplification and the 20 % squarewave amplitude modulation.

The sender-output (impedance 50 Ohms) is connected to a LC-resonance circuit which is part of the antenna-system. The inductance L is made up of a single wire loop of a geometry specifically designed for the intended application. In order to achieve maximum field strength within the range of the loop a high quality Q of the resonance circuit is required.

Figures 7 and 8 show the special cuff-shaped antenna array intended for the first clinical application with selected upper-limb injury patients.

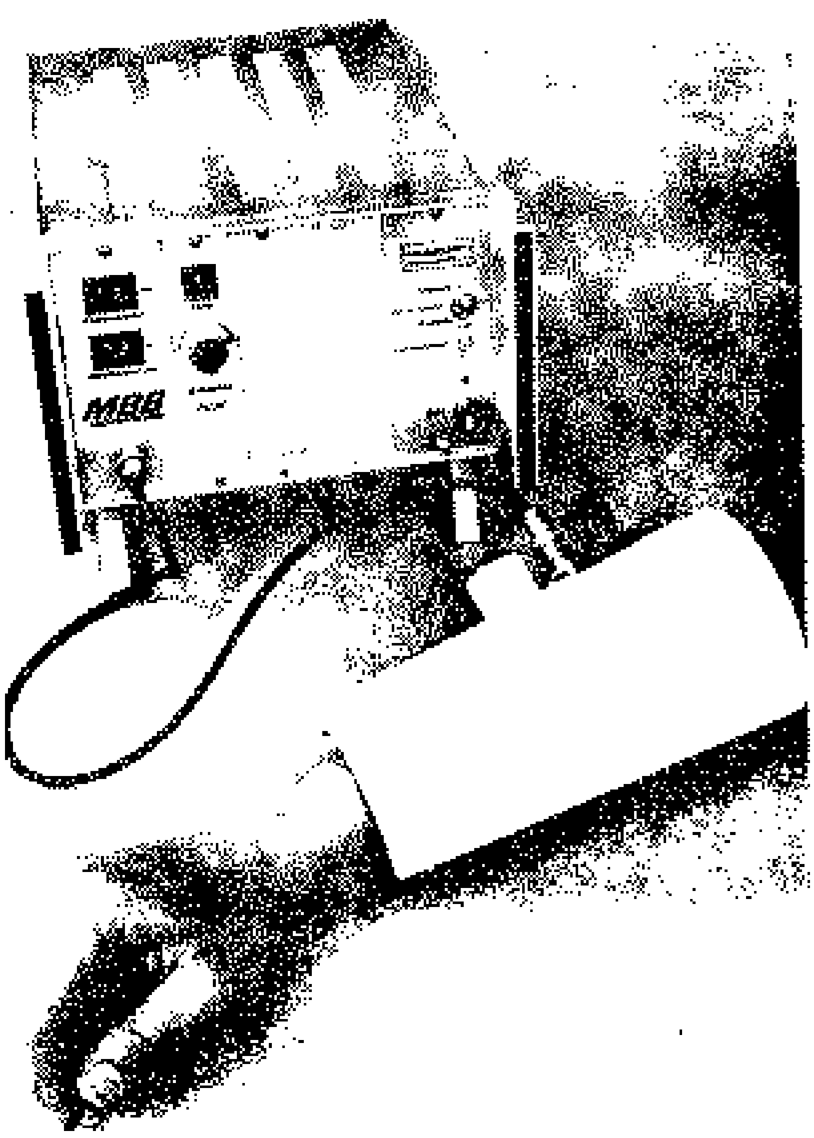


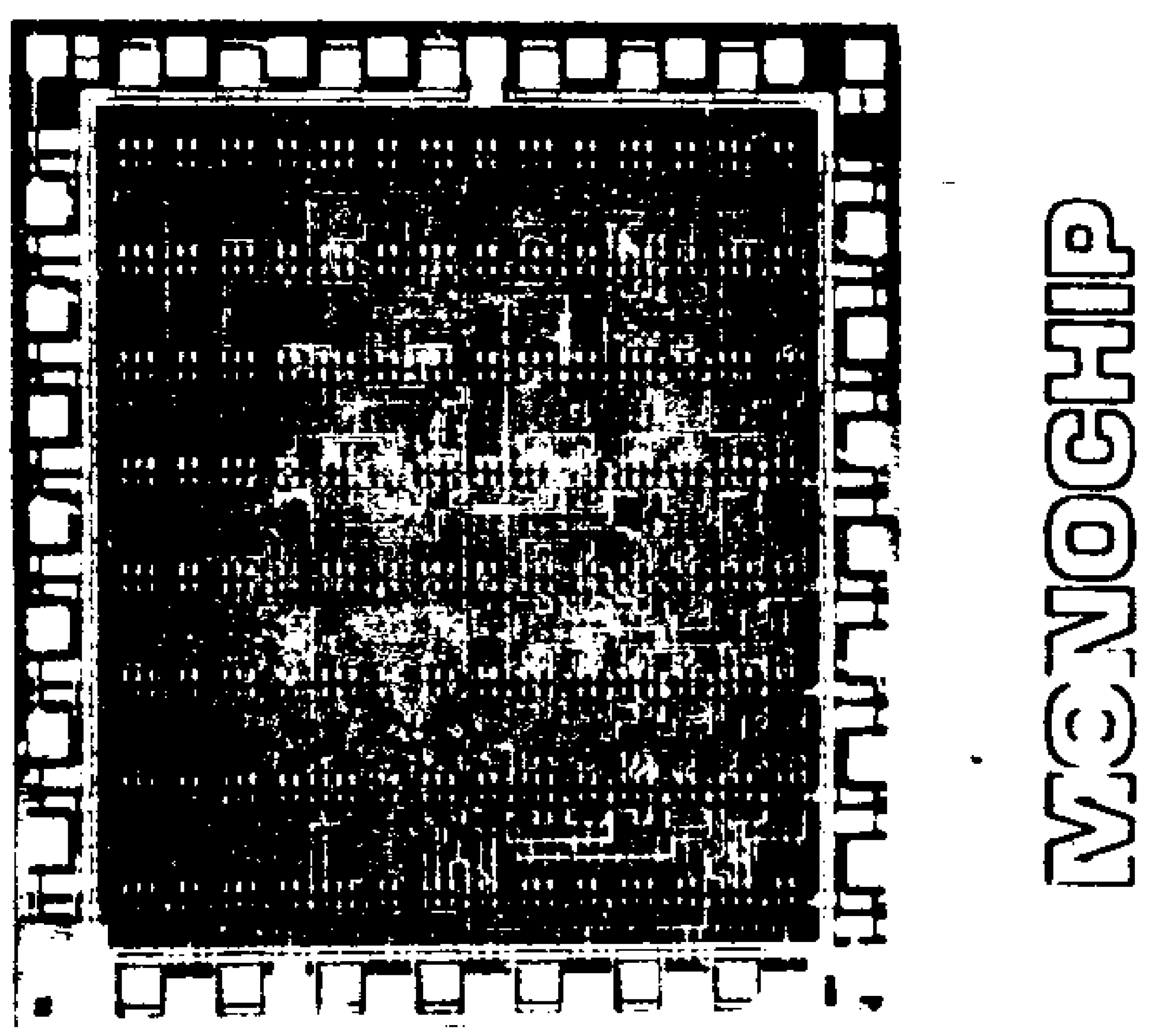
Fig. 7 Eight-Channel Sender and Cuff-Antenna

Fig. 8 Sender-Antenna Array with three adressable Stimulators in simulated Position

3. Miniaturization

3.1 Electronics

The development of a miniaturized 8-channel device was made possible only by utilization of at least partial electronic integration techniques, "blue chip" components, gold plated ceramic (Al_2O_3) substrates and ultrasonic micro-bonding. For decoding of the PCM-signal a specially designed MCA Monochip of the FERRANTI-
It contains 112 array cells, 14 driver
, one high impedance-cell and 4 corner
some 560 complementary N-MOS and P-MOS field-
dimensions



So far, 60 cells have been consumed for eight channels. With the remainder of 52 cells at least 6 to 7 additional memory units consisting of 1 DFF incl. reset (4 cells), 1 Ex-NOR (2 cells) and 1 AND (1 cell) could theoretically be added, allowing for an expansion of more than 500 channels !

Figure 10 shows an enlarged view of the miniaturized electronic package. On the left the receiving coil together with the equally visible capacitor forming the input resonance circuit, the diodes and buffer capacitors can be seen. At the right hand side the above mentioned Mono-chip for signal decoding, the constant current source (PUT) for charging the output capacitor components for internal clock-pulse generation the "large" energy storage capitor transistor chips and other components can be recognized.

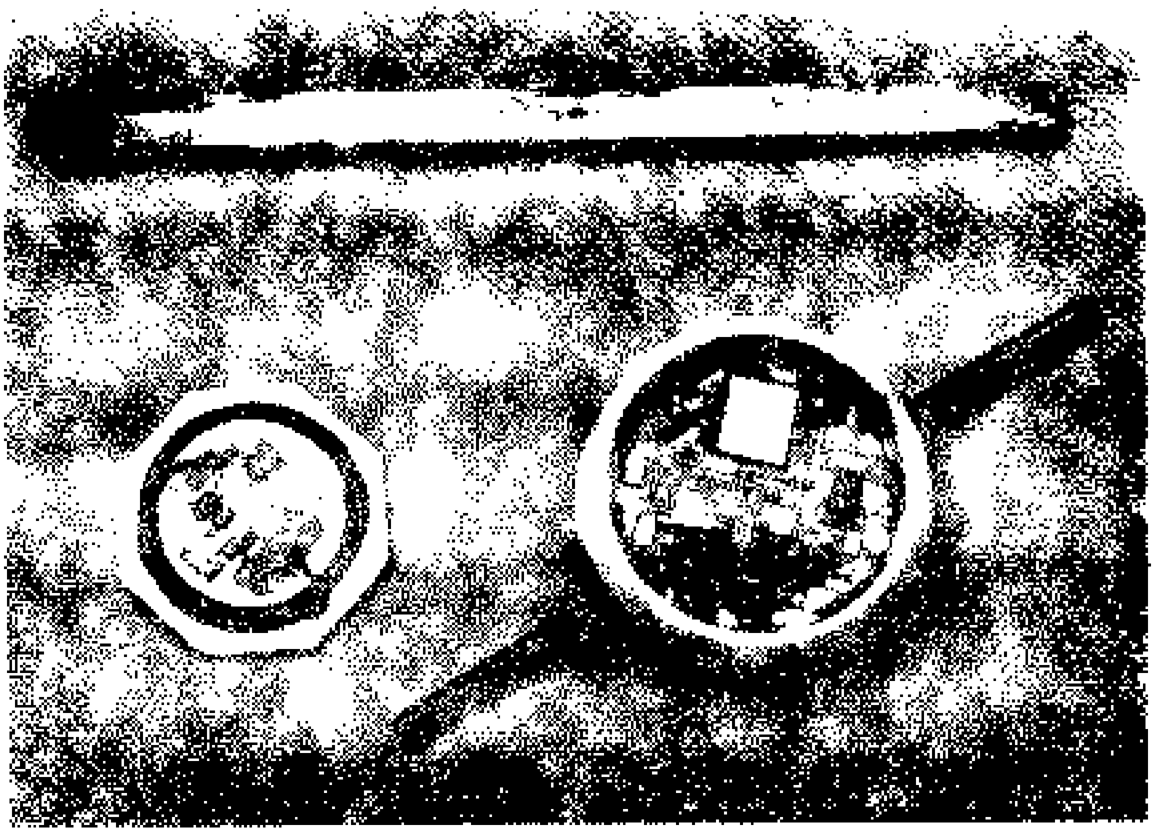


Fig. 10 Electronic Circuitry of the 8-Channel Stimulator
(left: input circuit, right: decoding and stimulation pulse generating circuits)

3.2 Encapsulation

biocompatibility as well as long-life
implanted in living tissue an encap-
been designed which makes use of an all
sealed housing with inserted titanium stim-
11 depicts the essential encapsulation
lab Prototypes the small ceramic cans have been
machineable glass-ceramics material MACOR produced by
bottom part and the lid are beeing
2 hours. The electrodes, after
circumference of the

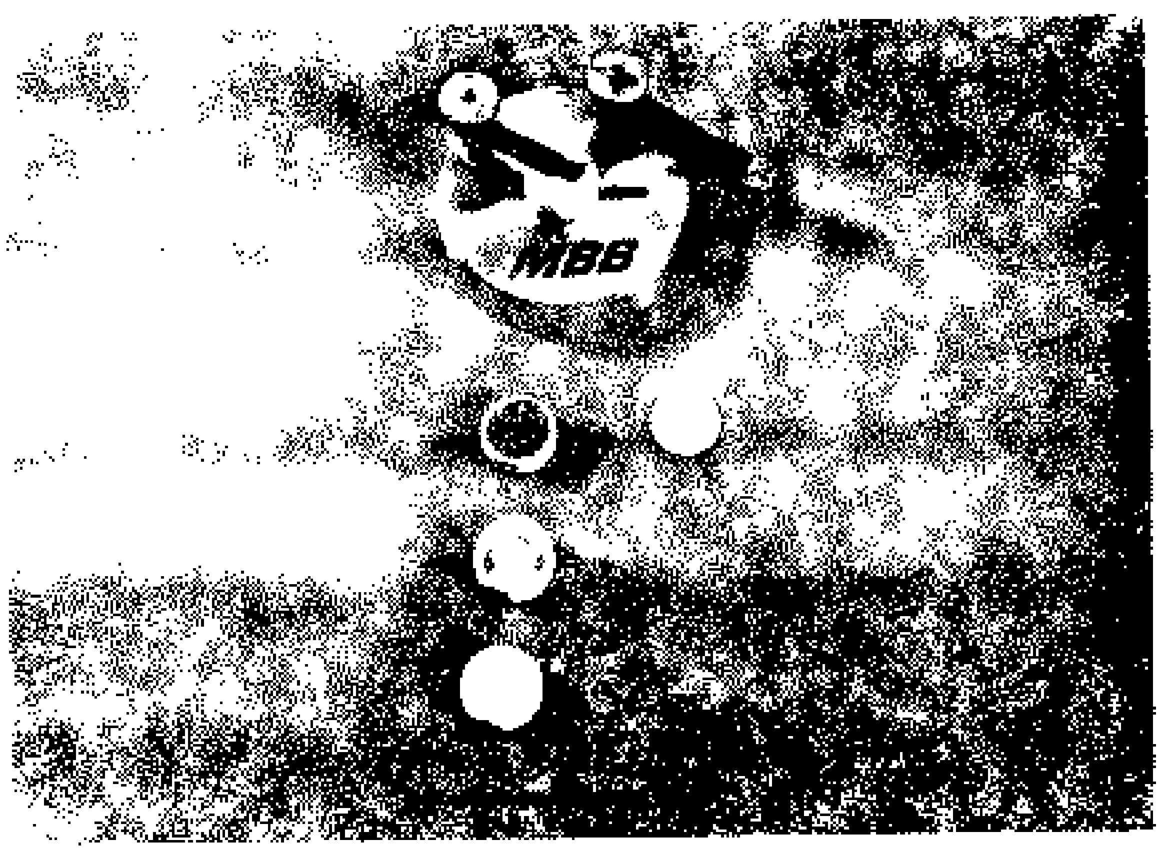


Fig. 11 8-Channel Stimulator Housing Elements and Electrodes box are beeing fused by adding a special glass solder at 670 °C (ca. 30 min.) in a muffle-furnace. Then the contact areas of the upper rim of the can and lid are beeing precoated with a low melting point glass at 450 °C for 5 to 10 min. The next step is insertion of the electronic hybrid-circuit into the box and soldering electrical output to the internal ends of the electrodes, including functional test. For protection against the process heat of the consecutive bracing of the lid to the housing, two circular Poly-imide foils are put onto the surface of the circuit. Subsequently the bottom part of the encapsulation is beeing centered in a stainless steel mold - heat sink - (Fig. 12), the partially glass-coated lid is put on, which is then fused by a heating die having a start temperature of approx. 700 °C within 40 seconds. The last process step provides a conformal coating of the whole device with DOW CORNING's non-corrosive, flowable, room temperature curing silicone rubber

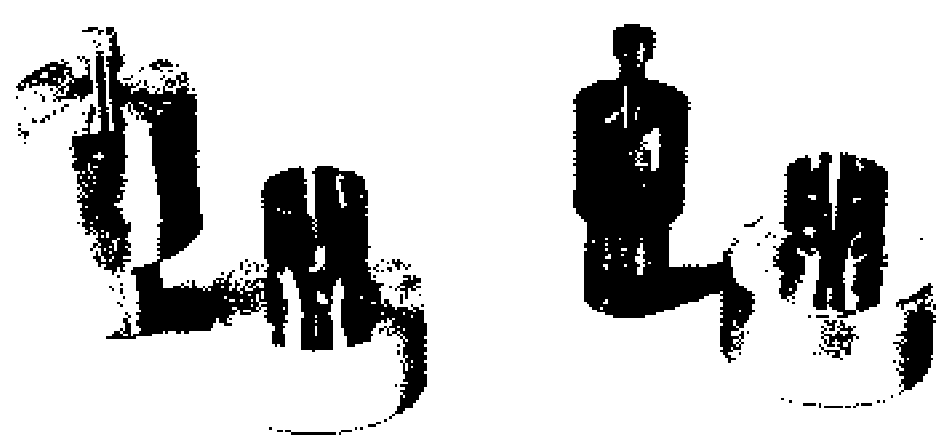
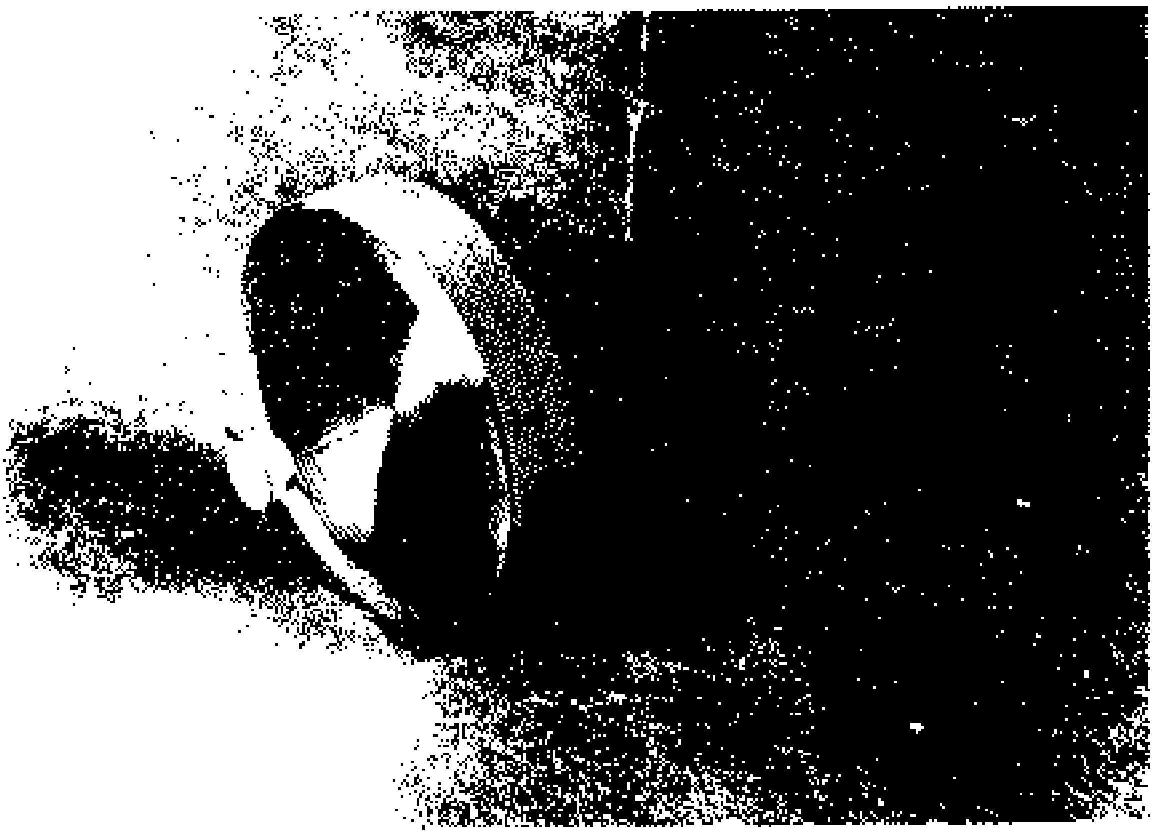


Fig. 12 Stimulator Encapsulation
Fusing Molds and Dies

4. He-Leakage Test

To make sure, that hermetic sealing is achieved, the stimulator goes through a He-leak test. For this purpose a glass capillary was fused to the bottom of the device previously (Fig. 13), which now is beeing connected with a He-source (pressure ca. 1.2 bar). The connection runs through the cover plate of the test chamber of a "VEECO" Mass spectrometer, leak detector (Fig. 14). During the full test time the internal cavity of the stimulator is beeing flooded by Helium. The leakage measured so far are less than 10^{-8} mbar/Lsec.



13 8-Channel Stimulator
Preparation for He-Leak Test

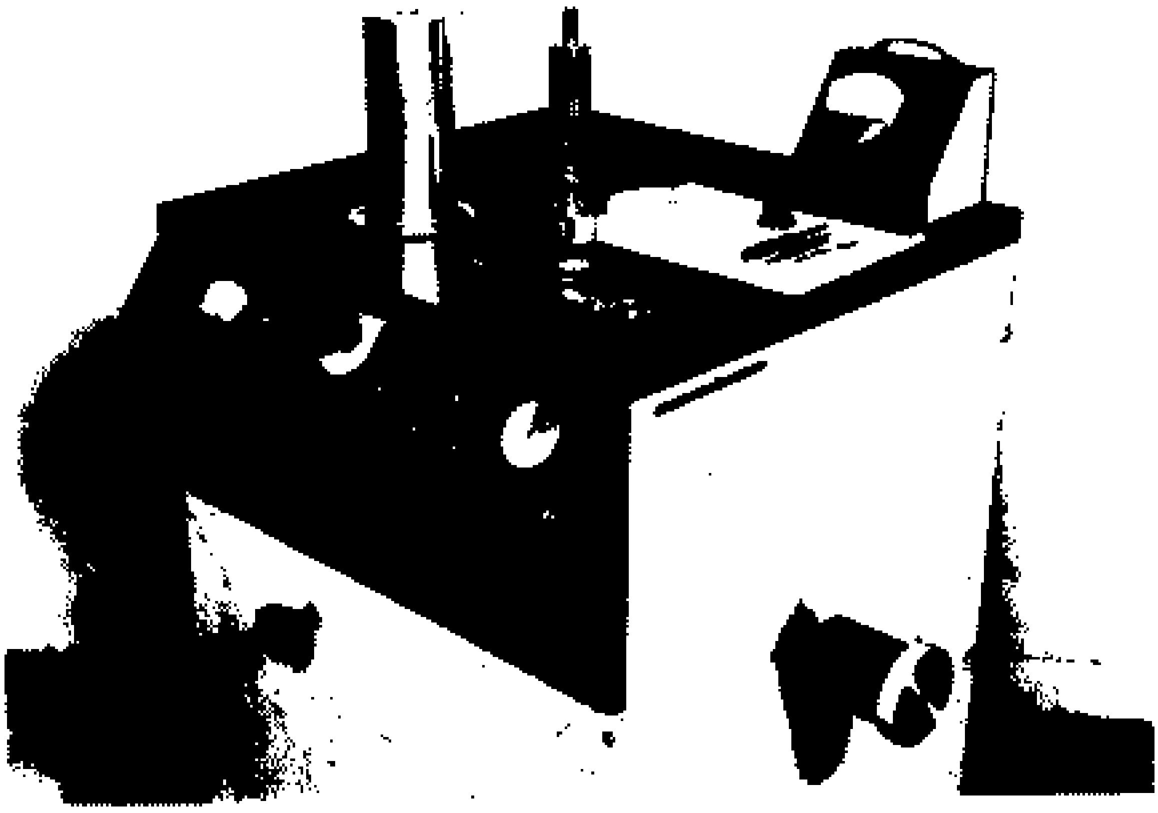


Fig. 14 "VEECO" He-Leak Test

5. Electrodes

The final electrode design comprising electrode materials and optimum electrode geometries has not been reached as yet. However important spezific evaluations have been carried out.

5.1 Electrode Materials

For material selection careful literature review as well as potentiostatic and potentiodynamic anodic polarization measurements with preselected materials were implemented. / 3 /

A total number of 10 different materials has been investigated, among others Ti, Pt/Ir, Ta, Au, stainless steel (V4A-Type), special Cr/Co/Mo-Alloy (implant material) and two types of vitreous carbon. These investigations and their detailed results will be published separately at a later point in time. According to our present knowledge, we are using a Ti/Pd-alloy, which is readily available and not too expensive for animal experiments. Besides its sufficient corrosion resistivity it has a fairly compatible thermal expansion coefficient, which is important with regard to the packaging technology. During animal test work with the "first generation stimulators" (one channel devices) we used helically wound stainless-steel wire of 100 µm wire diameter, 300 to 500 µm spiral diameter and of 32 to 40 cm length. However, 'in vitro'-endurance tests in buffered RINGER's solution at 38 °C as well as 'in vivo'-experiments in cats showed that under worst-case conditions - frequent or permanent generation of stimilating impulses of high amplitudes (above 10 V) and/or considerable mechanical loads (shear, bending forces) - these stainless steel electrodes did not withstand for very long times, i. e. for months and years, there were only few exceptions with a device-life of one to two years.

The above mentioned potentiostatic and potentiodynamic polarization measurements proved the facts. Therefore we changed in the "second generation" stimulators (8-channel devices) to Ti-electrodes.

However from the heart pace-maker research / 4 / as from our own investigations, Pt/Ir (10 %) alloy is equally suitable and so is Tantalum, the latter being a very intersting material insofar as it is prone of forming tantalum pentoxide at its surface / 5 /, therefore essentially eliminating oxidation-reduction reactions. Even if this did not work perfectly it should be possible to inject charge via the electrode surface in a way that the double layer at the surface is reversibly modified during biphasic pulsing. The Lit. / 6 / gives so-called "Theoretical non-gassing limits, which hopefully will be applicable.

5.2 Electrode Configuration

For obvious reasons - mechanical stability, ease of surgical handling and ease of production we altered the geometry compared with the 1st generation to simple pins of variable lengths and variable distances of the effective stimulating areas. Besides the rather simple reasons just mentioned, this electrode design offers the possibility to optimize the stimulation effect with regard to a defined muscular region by proper selection of the distance of the effective electrode-tissue interfaces from the generator housing or the mutual electrode distances respectively, as well as the corresponding effective electrode lengths. This can be done via evaluations of the generated field and current distributions / 7 /.

Literature

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