IMPLANTABLE MUSCLE/NERVE STIMULATOR AS A PART OF AN ELECTRONIC BRACE

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Summary

A stimulator for subcutaneous application was developed. It can be used with different types of electrodes as a muscle or nerve stimulator. The unit is radio-frequency powered externally controlled.

The thin film technology of passive elements for implantable stimulators was developed with the aim to obtain reliable and mechanically suitable units. For different applications we found some adequate types of muscle and nerve electrodes.

Only biologically stable materials were applied for encapsulation of the devices. A surgical technique which permits implantation of the stimulator with a minimum of trauma is described.

Functional electrical stimulation can in certain cases replace the classical braces and splints for the purpose of rehabilitation of patients with paralyzed muscles.

In the first successful attempts to control the muscle by electrical stimulation skin electrodes were used. This type of electrodes is used, for instance, in the Ljubljana Functional Peroneal Brace.

To avoid the problem of placing electrodes at the proper points, the inconstant electrode-skin resistance, and to decrease stimulating energy necessary, we decided on implantation of electrodes with the stimulator under the skin. Extensive experimental work has been performed since 1965, some of which was reported in Dubrovnik three years ago [1].

We have some experience with functional electronic peroneal braces that were clinically evaluated during the last few years, and with the neurophysological mechanisms which are known to some extent [2]. This is the only reason why we decided for the first time upon the application of an implantable nerve stimulator.

Our plan for the brace included an implantable stimulator with stimulating electrodes, an external transmitter for powering

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and control, and a radio-frequency switch to initiate the train of the stimuli.

We developed three different types of implantable stimulators:

1) Power source is a part of the stimulator [3];
2) Stimulator is RF powered in the rhythm of stimulating pulses [1, 4];

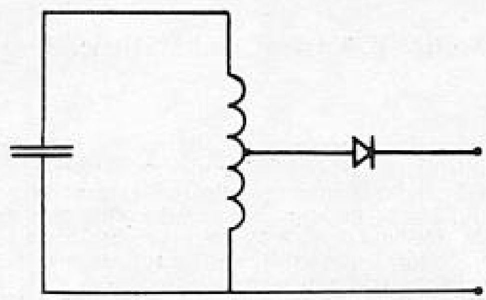

Fig. 1. The circuit of the stimulator

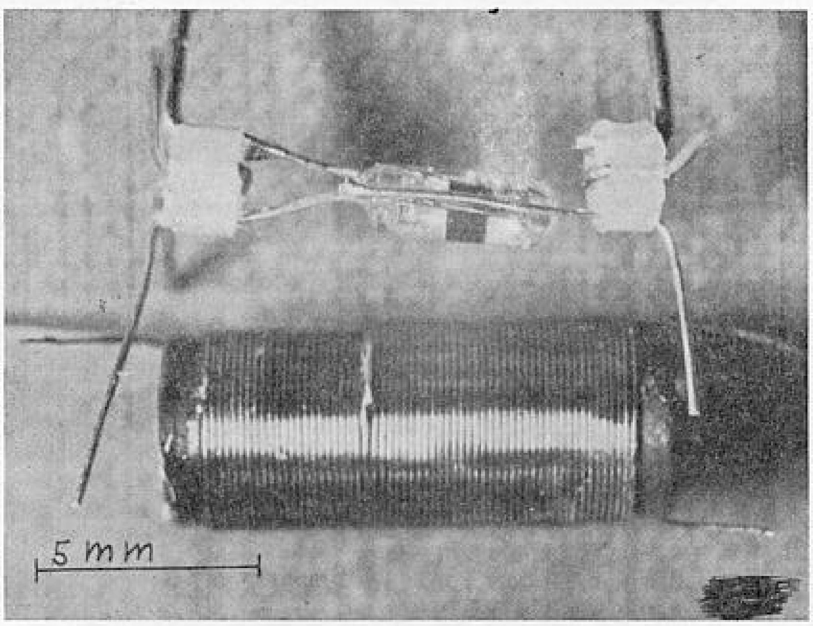

Fig. 2. The elements of the stimulator during mounting

3) Stimulator of higher performances is continuously RF powered during the train of the stimuli [5] (see Appendix I):

Because we estimate the implanted power source (mercury cells) to represent potential danger for the patient [4], we chose between types 2 and 3. For the reason of simplicity (low number of components) we chose the stimulator type 2.

It consists of the following elements: inductive coil L with a ferrite core in the form of a ferrite tube, capacitor of the tanked circuit, diode, and stimulating electrodes (Fig. 1).

The capacitor and diode were realized in a form of high ceramics plate with gold vacuum-deposited electrodes and diode dice bounded. All contacts are Au thermocompression-bonded wires. The unit is encapsulated in a glass tube provided with Ag connecting wires.

The elements of the receiver during mounting are shown in Figure 2.

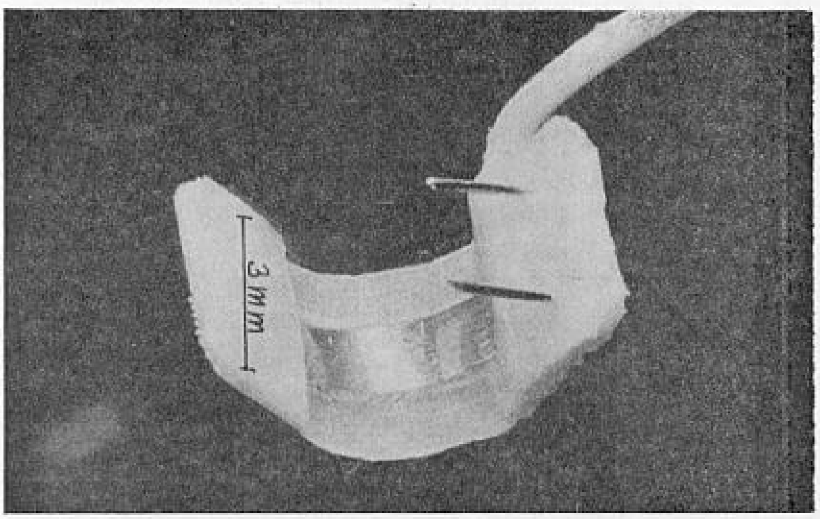

Fig. 3. Direct nerve electrode

For encapsulation we used Araldit E — Ciba with hardener HY 956. In spite of satisfying results of histological tests we used in human application Silastic Medical Grade coating of Dow Corning. In Radio Frequency Peroneal Brace (RFPB) we can use our direct nerve electrode (Fig. 3), or remote nerve electrode (Fig. 4).

The electrode in Figure 3 (one or two Pt tapes on a silastic sheet which envelops the nerve trunk) permits very low exciting voltage. The electrode in Figure 4 is Pt wire wound on the poles of the stimulator and permits implantation with very little trauma to the patient.

The parameters of the stimulator were determined by measurements with subcutaneous and cutaneous electrodes in the region of fossa poplitea behind the head of fibula (Fig. 5).

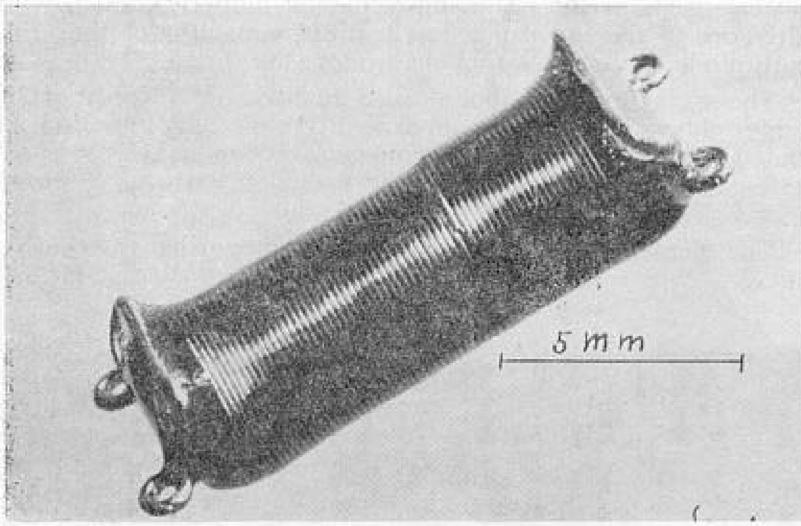

Fig. 4. Stimulator with remote nerve electrodes

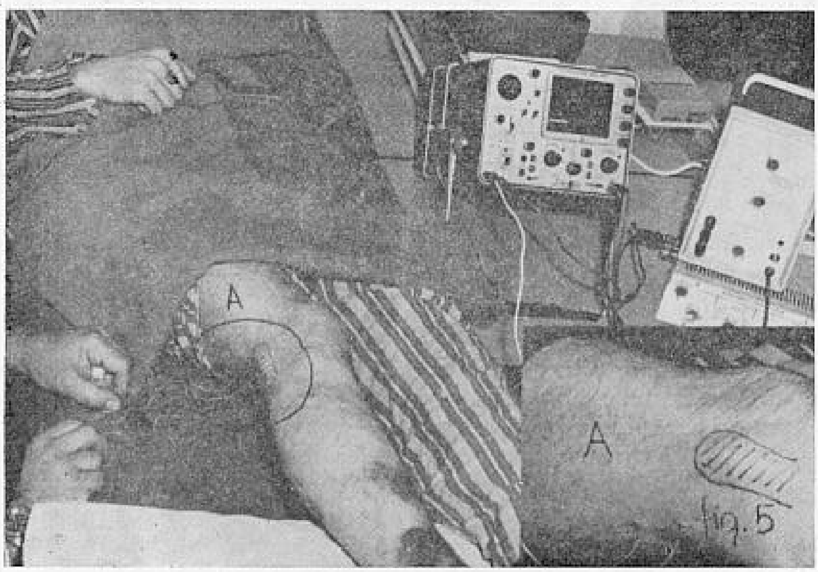

Fig. 5. Measurement of the parameters with cutaneous and subcutaneous electrodes

For different frequency, pulse duration T, and amplitude of stimuli, the moment in ancle joint at dorsal flexion was measured. The dynamic properties of the muscle response were studied. Two examples of the muscle response for cutaneous and subcutaneous electrodes are shown in the diagram in Figure 6.

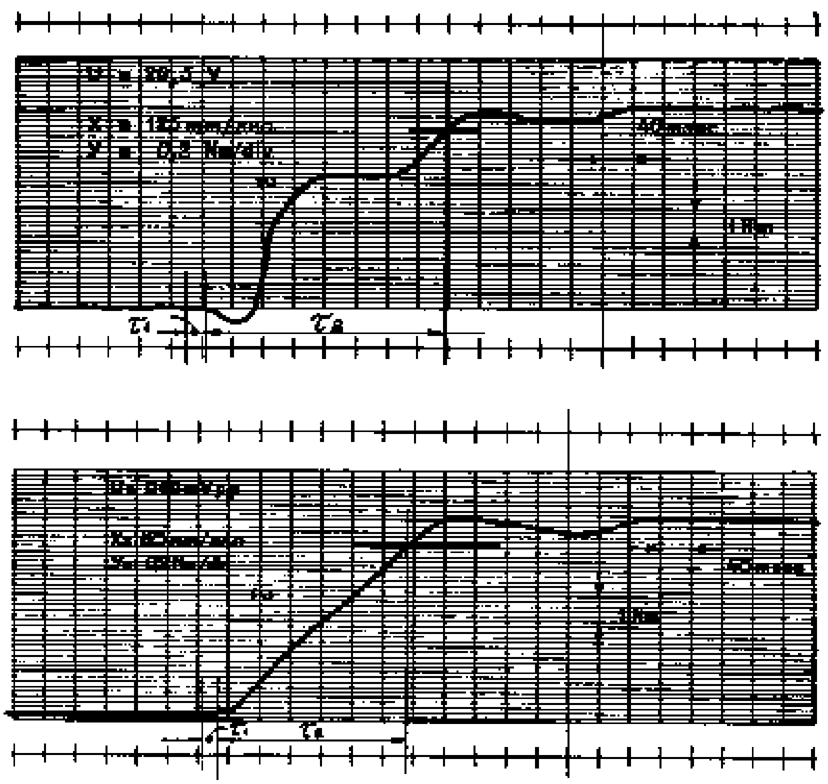

Fig. 6. Measurement of the muscle response with cutaneous and subcutaneous electrodes

The amplitudes provoking the same moment at cutaneous and subcutaneous stimulation are 0.3 — 3 V and 21 — 55 V respectively.

The comparative measurements were performed on normal subjects and on patients after central lesion to determine the level difference in both.

The dimensions and form of stimulator were determined on the base of measurement of Φ in ferrite cores of different sizes (see Appendix II) [6]. When determining the final dimensions and form, we had to consider also the requirements of the surgeon.

The circuit diagram of the transmitter part of the stimulator is shown in Figure 7.

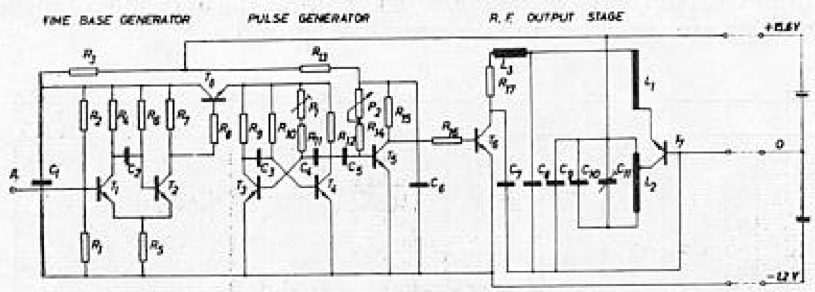

Fig. 7. The circuit diagram of the transmitter

The first monostable multivibrator is determining the duration of train of the stimuli in the switch mode of operation. The proportional control can be realized in modulating part T_6.

The switching signal is fed to the monostable multivibrator from the output of the receiver of RF switch.

The inductive coil is in a form of an elastic band, to be placed under the knee, and connected with the transmitter stimulator by a cable. The RF switch is placed under the heel in a plastic sock placed in the shoe, Fig. 8, on which the parts of RF peroneal brace are presented.

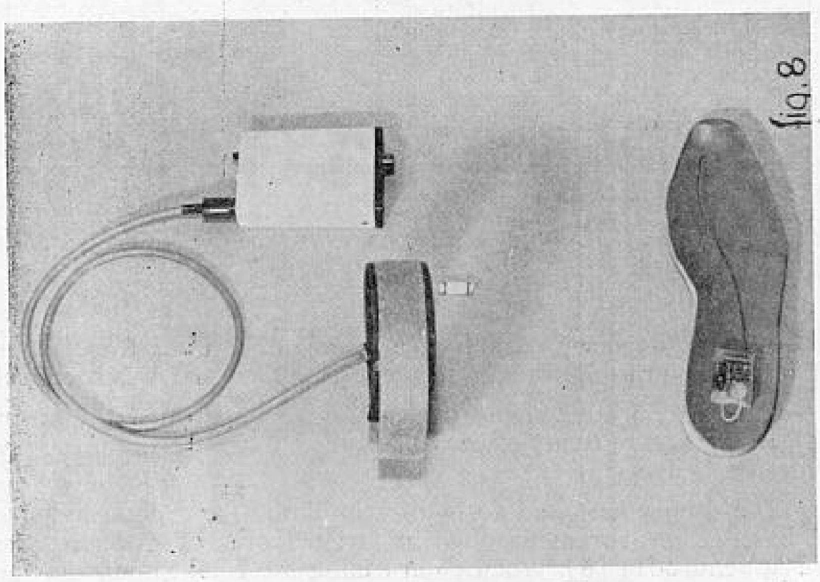

Fig. 8. The parts of RF peroneal brace

Rechargable Ni Cd batteries are used.

The RF switch transmitter operates at 100 MHz. It is powered by Mallory Mercury cell, in normal conditions lasting 1 year (Fig. 9).

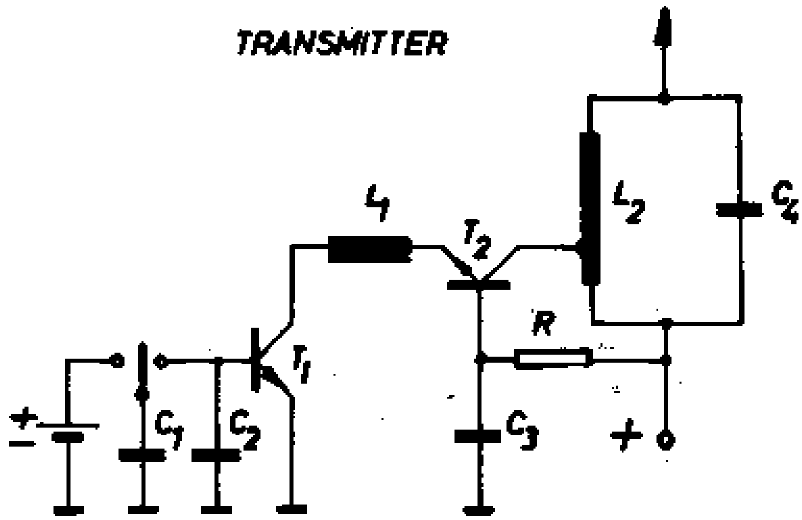

Fig. 9. RF switch transmitter circuit

Implantation Technics

The stimulator must be manufactured in clean room conditions. Bofore implantation it must be sterilised by immersion into cetaulon solution for 24 hours, or by hot sterilising procedures. After sterilisation the functioning of the stimulator must be tested again.

The patient is prepared in the operating room. The local anasthesia is introduced just behind the head of the fibula. One per cent xilocain can be administered. After the location of the region which permits the control of the tibialis anterior nerve by means of subcutaneous electrodes, transversal incision of skin and subcutaneous tissue of 12 mm is performed behind the head of the fibula, (Fig. 10), followed by tunnelizing in proximal and distal direction of 1 cm.

Into the tunnel formed in the subcutaneous tissue, the stimulator is inserted. The stimulator being fixed to fascia by Ethicon sutures (Fig. 11).

The wound is provided by sterile closure. The sutures are removed after 7 days when the control of operation of the stimulator begins.

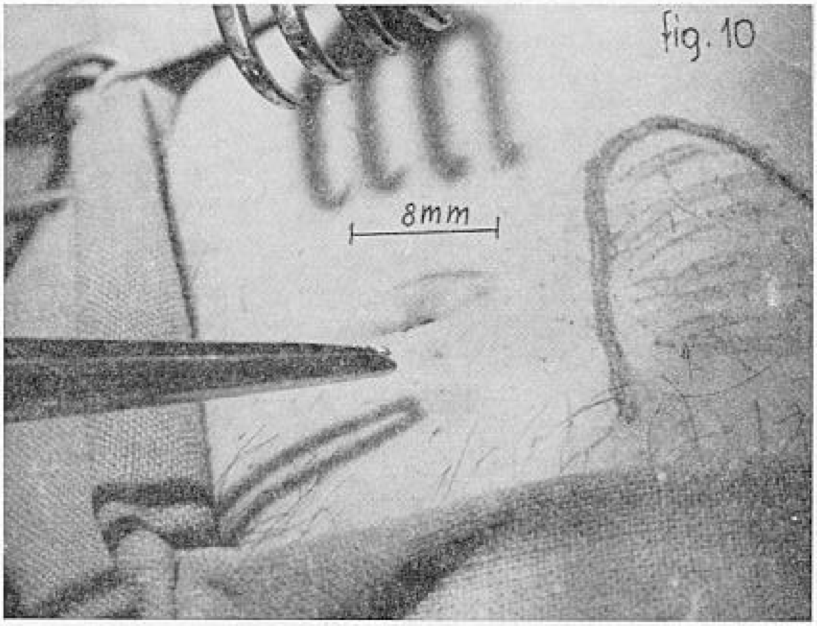

Fig. 10. Skin and underskin incision

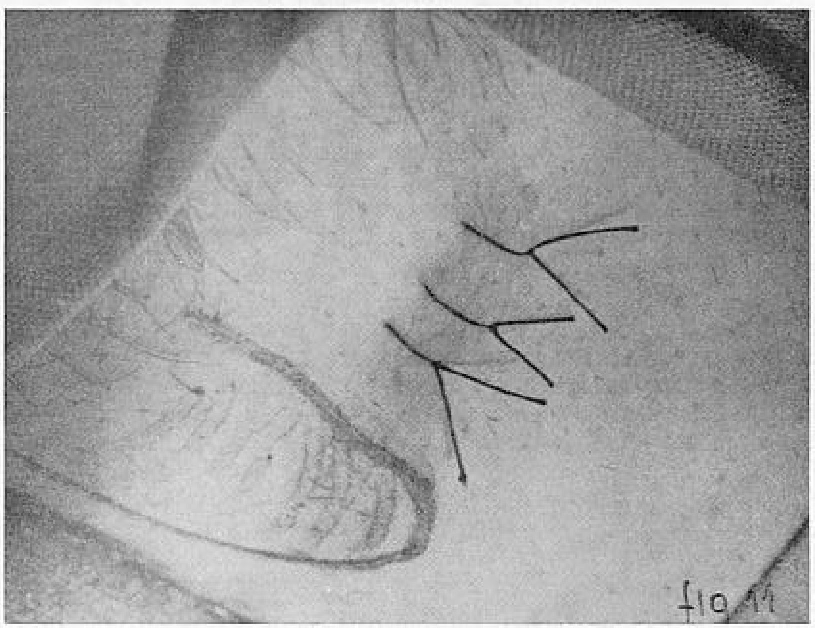

Fig. 11. The sutures of the skin

The first stimulators were implanted into the legs of volunteers. The stimulators were implanted as a part of RF electronic peroneal brace (Fig. 12).

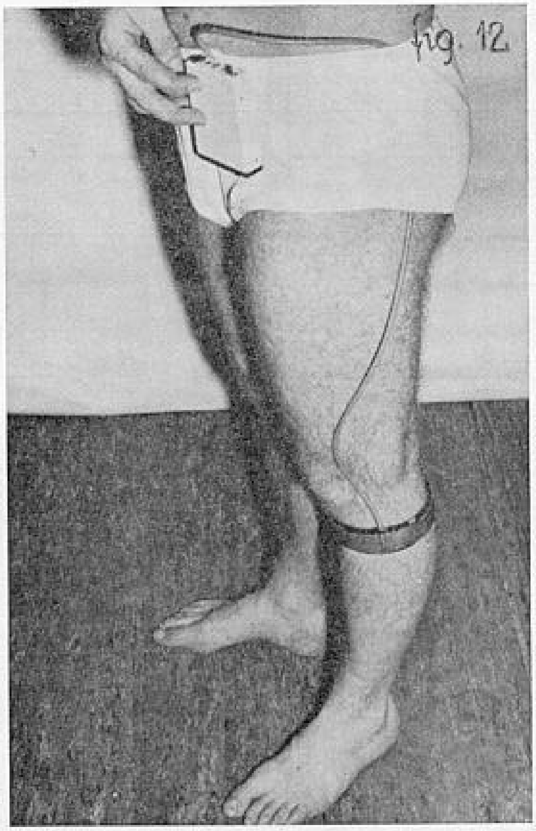

Fig. 12. RF electronic peroneal brace

So far we do not know, what we may expect from a brace of which a part is integrated into the body.

If the evaluation of the results of the long term experiment is satisfying, the application in a patient would be possible. However, there must be clear indications for implantation from the medical point of view.

APPENDIX I

If the stimulator has a simple form of tanked circuit, (Fig. 1), the energy is delivered during time interval T_2, which is the operation interval of the transmitter. The output voltage has a form of sinus rectified.

In the type III. of the stimulator the transmitter is set on time intervals $T_1 - T_2$.

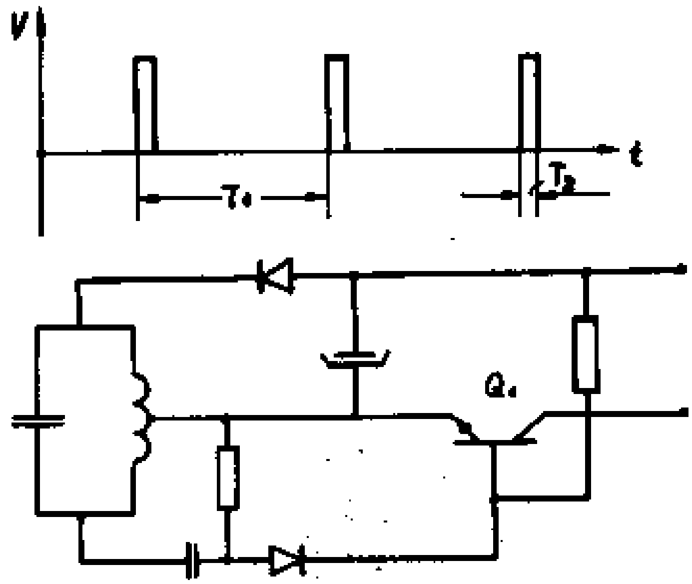

Fig. A—1. CDT stimulator

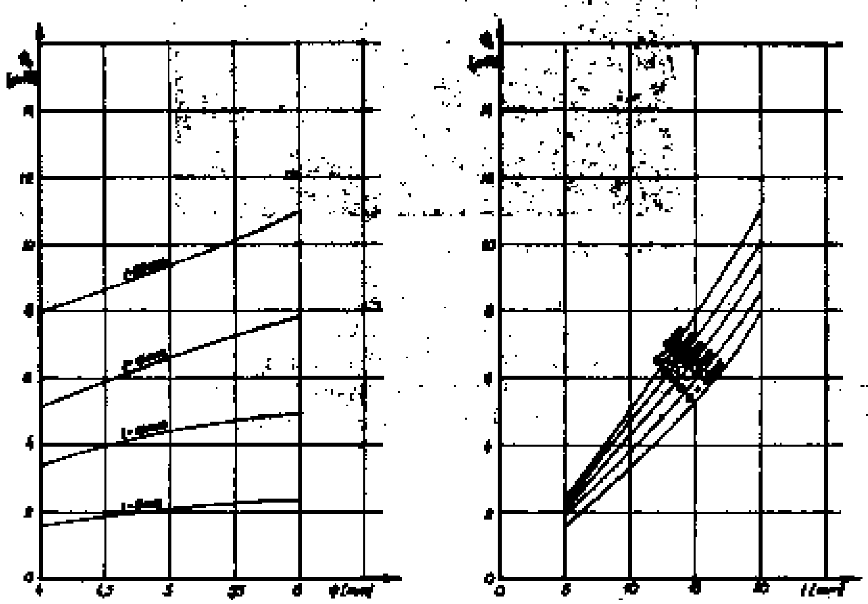

Fig.A—2. The diagram of magnetic flux as a function of length and diameter of the ferrite core.

The energy is accumulating in the capacitor. The output is switched off through Q_1, which is a Darlington amplifier, in the time interval T_t, the transmitter is switched off, negative bias on the base of Q_1 disappears, Q_1 switch is on. The output voltage is DC in a form of rectangular pulses.

For stimulator types 2 and 3, as described above, the output power ratio can be some hundreds to even some thousands dependent on f, T, C, and magnetic field density B.

APPENDIX II

In the axis of a transmitter coil magnetic field density B and magnetic flux Φ were measured without and with a ferrite core. Different sizes of ferrite cores were used.

We see that Φ is a function of length L and diameter of the ferrite core. The output power ratio for the receiver with and without ferrite core $\frac{P_f}{P_0}$ was measured [6].

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