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Self-Synchronizing Cardiac Pacemaker

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***Abstract*—A new kind of cardiac pacemaker for direct heart stimulation in cases of intermittent or variable heart block is presented. The pacemaker is capable of providing stimuli either synchronously with ventricular depolarization or at a fixed rate when natural pacing fails. Thus any competition between artificial and physiological rhythm is avoided, while allowing the exploitation, from the hemodynamic viewpoint, of the surviving capability of physiologic control of the heart rate. The main features of the instrument are that the shifts from synchronous to free operation and vice versa take place in an automatic way, and no electrode besides those which provide stimulation are needed for synchronization. The mean power consumption of the pacemaker is comparable with that of conventional unsynchronized pacemakers. Thus the subcutaneous implantation is possible, with a theoretical lifetime of 30 000-hour autonomy. Schematic diagrams and waveforms are included.**

I. Introduction

HEART stimulation in the presence of complete heart block has been discussed by many authors [1]–[13], and cardiac pacemakers of various kinds have been designed for permanent heart stimulation at a fixed pulse rate. However, the use of such pacemakers in the presence of intermittent or variable heart block is difficult because of the possibility of conflict between conducted stimuli of sinoatrial origin and external stimuli (*ES*) produced by the pacemaker. Some ways for avoiding this difficulty have been proposed and experimented by using various kinds of adjustable apparatus [14]–[16] or atrial triggered pacemakers [17]. We suggested a new way [18] of avoiding this conflict without inhibiting conducted stimuli, that is, to implant a pacemaker capable of being synchronized by possible ventricular depolarization signal (*VS*). This mode of operation allows the exploitation, from the hemodynamic standpoint, of the surviving capability of physiologic control of the heart rate, thus making the prothesis action closely similar to physiologic behavior.

The aim of the present paper is to describe a pacemaker capable of producing stimuli either synchronously with ventricular depolarization or at a fixed rate when *VS* fails. The main features of this new cardiac stimulator are that the shifts from synchronous to free operation and vice versa take place in an automatic way, and no electrode besides those which provide stimulation are needed for synchronization.

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II. Principles of Operation

The pacemaker consists of two main circuits (Fig. 1):

1) The amplifier and pulse-forming circuit *A*. This circuit amplifies the signal of physiologic origin, *VS*, present between terminals *a* and *c*, and makes it able to synchronize *ES*. Since *VS* changes in amplitude and shape with patient and time, it must be standardized before being used for synchronizing *M*. This is obtained by generating a standard synchronizing pulse *S* for each *VS*.

2) The multivibrator *M*, capable of being synchronized. This circuit supplies signal *ES* between terminals *b* and *c* for heart stimulation.

The system can also operate with terminals *a* and *b* connected together according to the block diagram in Fig. 2. Thus the same electrode which provides stimulation picks up the physiological stimulus. With either circuit realization (Fig. 1 or Fig. 2), signals produced by *M* are synchronized with possible *VS*, provided the rate of *VS* is not less than a pre-established value. When this occurs, or when *VS* is absent entirely, *M* supplies *ES* at a fixed rate.

In the following we shall refer to the operating mode shown in Fig. 2, since this mode of operation both represents the peculiarity of this pacemaker and is the most important feature from the clinical point of view.

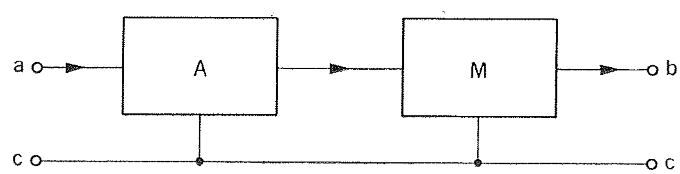

Fig. 1. Block diagram of the self-synchronizing cardiac pacemaker. Block *A* is the amplifier and pulse-forming circuit. *M* is the synchronizable multivibrator.

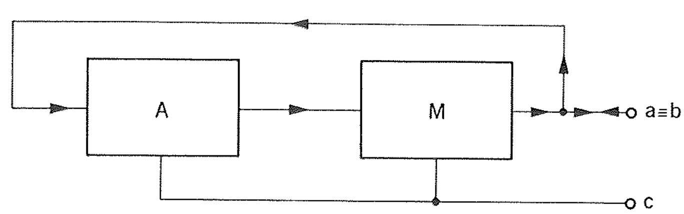

Fig. 2. Block diagram of the self-synchronizing cardiac pacemaker connected for mono-electrode operation.

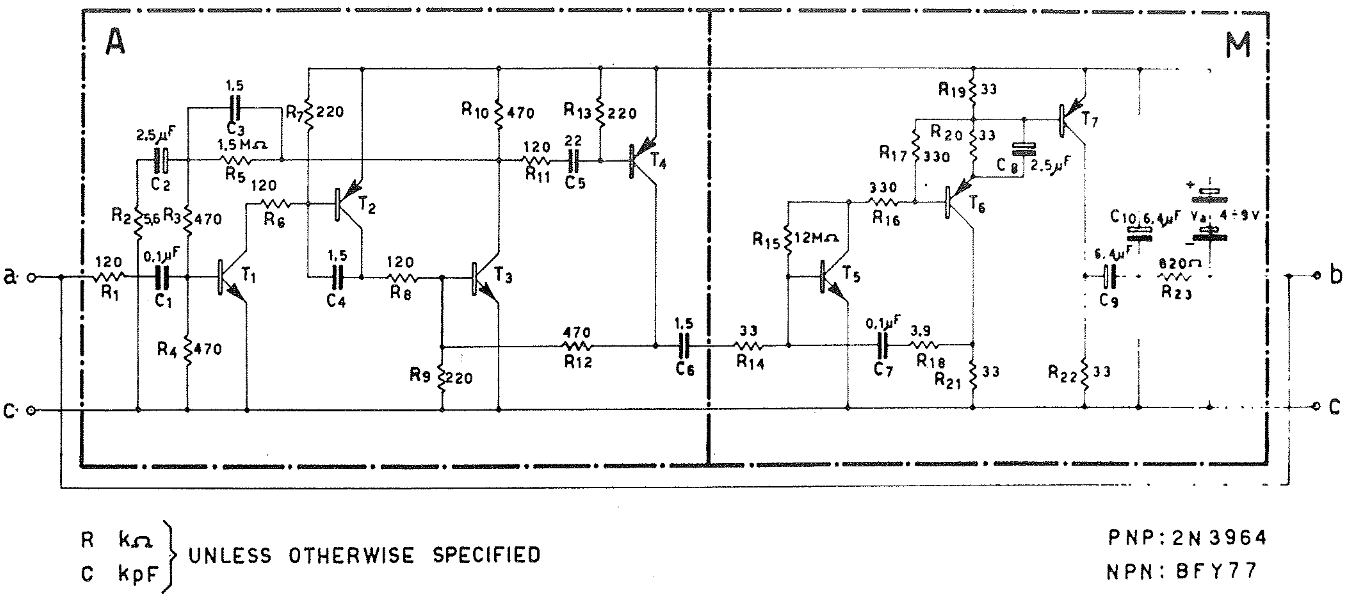

Fig. 3. Circuit diagram of the pacemaker. Section A is the amplifier and pulse-forming circuit. Section M is the synchronizable multivibrator circuit.

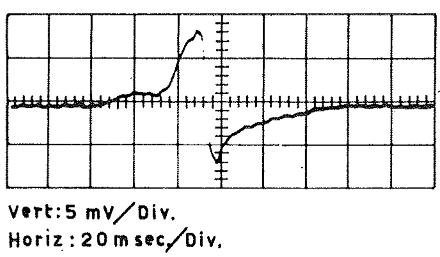

Fig. 4. Ventricular depolarization signal picked up through intracavitary electrode.

III. The Circuit

In circuit packaging, either conventional or integrated, the major difficulty is met by introducing inductors and capacitors. For this reason we have studied a circuit which needs no inductor while using few capacitors. Such a feature has been obtained by using complementary transistors (*P-N-P* and *N-P-N*) with direct coupling for the first three stages of the amplifier and for the multivibrator circuit.

Amplifier and Pulse-Forming Circuit

The electrical diagram of the pacemaker is shown in Fig. 3. The portion labeled *A* refers to the amplifier and pulse-forming circuit.

A ventricular depolarization signal picked up through an intracavitary electrode, such as *VS*, generally presents the characteristics reported in Fig. 4. To generate *S*, it is useful to employ the faster portion of *VS*; this means that the amplifier must exhibit a bandpass from about 40 to 80 Hz. On the other hand, the amplitude of *S* must be on the order of some volts with equivalent resistance of about 10^4 ohms, while the amplitude of *CS* is some millivolts with equivalent resistance on the order of 10^3 ohms. Therefore a power gain on the order of 40 dB is needed.

Circuit *A* employs four transistors, $T_1, \cdots, T_4$. T_1 and T_2 act as amplifiers only. T_3 both amplifies *VS* and, together with T_4, generates *S*.

T_3 and T_4 operate as follows: as long as the changing rate of *VS* is less than 0.2 volt/s, T_4 is in the cutoff condition, and T_3 acts as the third stage of amplification. As soon as the changing rate of *VS* exceeds 0.2 volt/s, T_4 starts to conduct so that a positive feedback occurs between T_3 and T_4. This causes an 8-volt, 4-ms pulse to appear at the collector of T_4. Such a pulse triggers the multivibrator *M*.

Lower and upper limits of the bandpass of the amplifier are determined by the values of the time constant in the input circuit (R_1C_1) and by that of the time constant in the feedback loops (R_5C_3), respectively. Capacitor C_4 assures circuit stability at high frequencies.

In the range of frequencies to be amplified, the feedback network limits the voltage gain of the first three stages to 700 with a feedback of about -30 dB. Due to C_1 and C_2 the dc feedback is about -78 dB. This assures the proper operation of the circuit between 0 and 75°C.

The introduction of silicon 2nd planar transistors allowed very low biasing collector currents (about 2.5 μA for T_1 and T_2, and about 5 μA for T_3). With such currents high-input impedance has been obtained for the first transistor; as a consequence, it has been possible to have a much greater amplificator input impedance (about 100 kilohms) than the characteristic resistance of intracavitary electrode (between 200 and 500 ohms). The current drain of the amplifier and pulse-forming circuit is about 15 μA when an 8-volt battery is used.

It can be noticed that the same results could be obtained with fewer transistors. However this would require much greater biasing currents than those we have chosen, thus making power supply problematic. Moreover, the presence of four transistors allows the introduction of considerable negative feedback among the stages working in linear condition, thus making the circuit independent of transistor characteristics over a wide range.

One of the main features of the amplifier is the recovery time following overdriving conditions, since the amplitude of the input signals to A may reach some volts when the input of A is connected to the output of M (Fig. 2). After the application of the maximum signal that the multivibrator can supply, the amplifier recovery time must be such as to permit correct amplification of signals that are separated by time intervals equal to the minimum stimulation period. As will be seen, the maximum stimulation frequency is limited to 2.5 Hz for avoiding too rapid ventricular rate in the presence of abnormal atrial rhythms. Therefore recovery time smaller than 0.4 second is required. With the values of the components of the input circuit which appear in Fig. 3, a recovery time less than 0.15 second has been obtained.

Multivibrator

Section M of the circuit diagram in Fig. 3 refers to the multivibrator circuit. This is realized in the usual way, that is, by two complementary silicon 2nd planar transistors which reduce the current absorbed in rest conditions to a minimum. Another transistor decouples the load from multivibrator circuit. The current drain of the M circuit, when this is unloaded, is about 3 μA. In the maximum loading conditions and at repetition frequency of 1.3 Hz, the mean current drain of M may reach 15 μA. All this is based on the use of an 8-volt battery.

The multivibrator supplies a standard biphasic pulse whose duration and repetition rate characteristics are determined by R_{15}, R_{18}, and C_7. Time constant $R_{18}C_7$ determines the duration T of the pulse, while time constant $R_{15}C_7$ determines the frequency f_0 of ES in absence of VS. With the values reported in Fig. 3, $T=2.5$ ms; $f_0=1.2$ Hz.

The group $R_{20}C_7$ stabilizes circuit operation against changes in the β of transistors, temperature, and battery voltage.

Resistor R_{23} limits the maximum value of output current, thus making stimulation more independent of the contact resistance of the stimulating electrode. When picking up VS through the stimulation electrode, the multivibrator output circuit is parallel connected with the amplifier input circuit, and therefore high output resistance is required for M in rest conditions. This requirement has been taken into account in designing the output circuit (R_{22}, R_{23}, C_9).

To synchronize ES, the synchronizing pulse S appearing at the collector of T_4 is added to the signal that is present at the base of T_5 because of the charging of C. The voltage dividing network R_{14}, $R_{18}+R_{21}$ causes the multivibrator not to be fired at frequencies higher than 2.2 f_0. When frequency f_v of VS is higher than 2.2 f_0, then M fires at a frequency f_e submultiple of $f_v (f_e=f_v/N; N=1, 2, \cdots)$. Hence, frequency f_e of ES satisfies the following relation:

$$f_0 \leq f_e \leq 2.2 f_0.$$

When $f_v < f_0$, a regular cycle is established by the dead time of the pacemaker and by the myocardium refractivity. In this cycle a conducted stimulus occurs for every 1 or 2 pacemaker stimuli.

IV. Experimental Results

Figure 5 reports the voltage gain versus frequency characteristic of the three amplification stages (T_1, T_2, T_3). The bandpass at -3 dB is from 18 to 90 Hz and is fully compatible with the characteristics of the signal to be amplified.

The recovery time of the amplifier following the overdrive caused by the multivibrator pulse has been verified by connecting the system as shown in the block diagram in Fig. 6. Experimental results are shown in Fig. 7.

Figure 8(a) and (b) shows how T and f_0 change when varying battery voltage and current amplification factor of transistors. In the range of temperature from 15 to 75°C the percentage change of T is 0.12 percent/°C, that of f_0 is -0.075 percent/°C.

Figure 9 shows some pieces of electrocardiogram of a patient affected by variable heart block. They clearly show that pacemaker operates at its own rate when heart block occurs, while synchronized operation gradually takes place in the presence of conducted stimuli of sinoatrial origin.

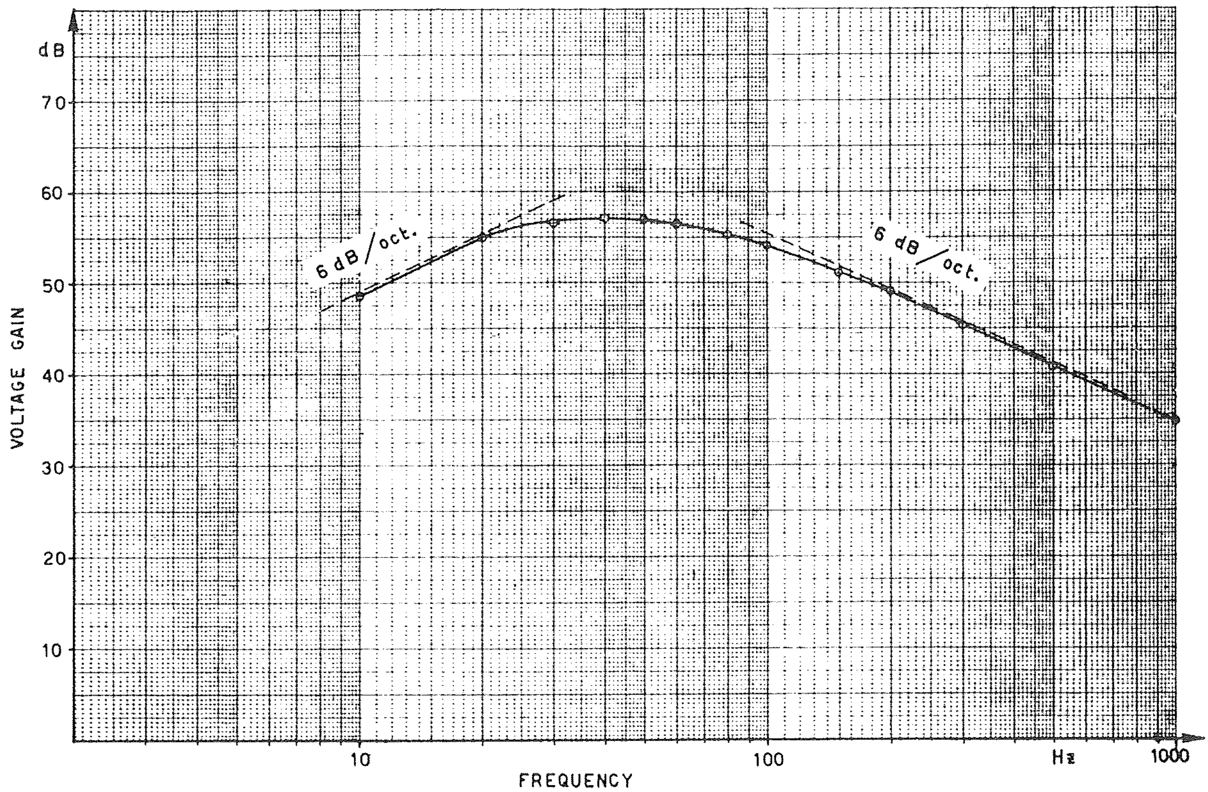

Fig. 5. Voltage gain versus frequency characteristic of the amplifier circuit. Output signal is picked up at the collector of T_3 with T_4 disconnected (see Fig. 3).

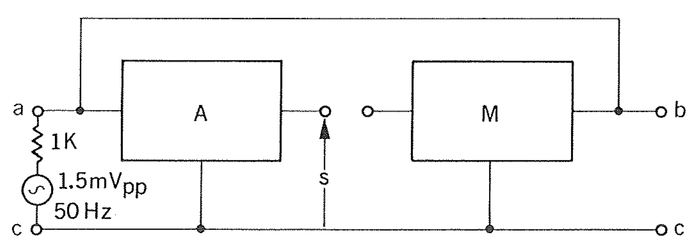

Fig. 6. Block diagram showing the connections for experimental measurement of the recovery time following an overdriving condition.

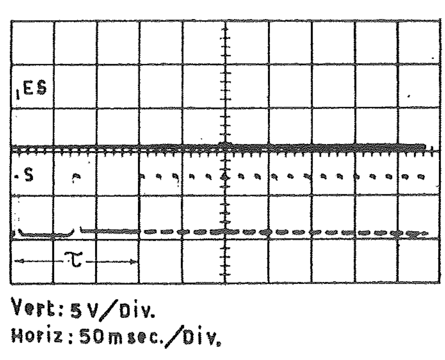

Fig. 7. Recovery time (τ) of Section A of the circuit in Fig. 3. The waveforms are obtained by connecting the pacemaker according to the block diagram in Fig. 6.

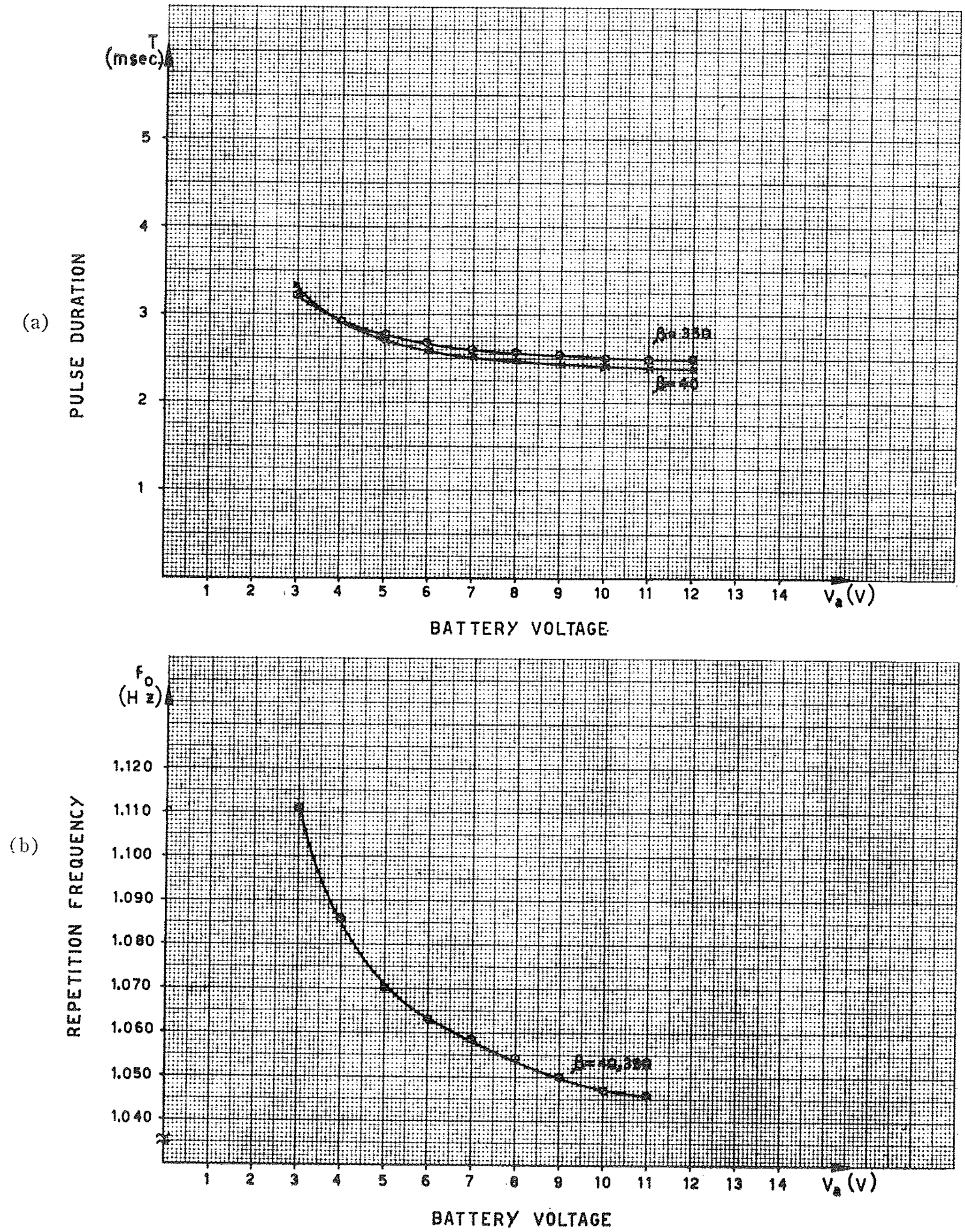

Fig. 8. (a) Duration of the artificial pacing pulse versus battery voltage and current amplification factor of the transistors (β). The characteristic refers to the multivibrator circuit shown in Section M of Fig. 3.

(b) Repetition frequency of the artificial pacing pulse versus battery voltage and current amplification factor of the transistors (β). The characteristic refers to the multivibrator circuit shown in Section M of Fig. 3.

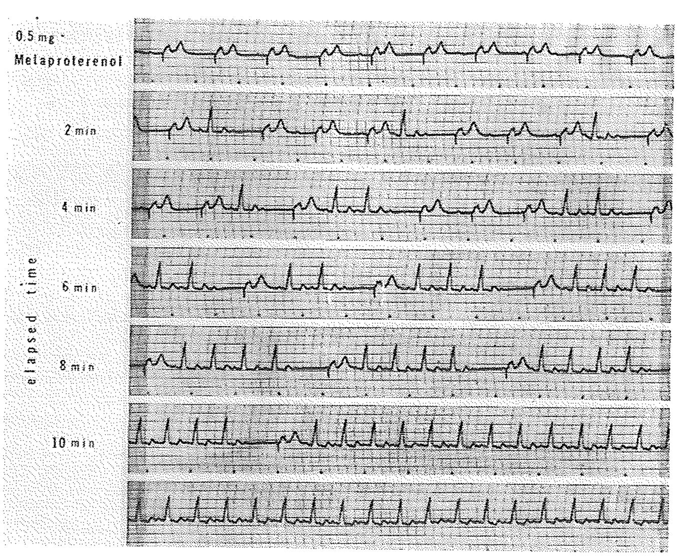

Fig. 9. ECG recorded during the shift from free to synchronized pacemaker operation when 0.5 mg of Metaproterenol are injected via i.m. to improve atrial-ventricular conduction. The first strip refers to complete atrial-ventricular block condition. In the last strip the natural atrial-ventricular conduction is completely operating. The kink of the R wave shows the firing time of the artificial pacing pulse.

V. Conclusions

The pacemaker described above should meet wide application both in the treatment of variable heart blocks and in exploring the possibility of restoring or improving atrial-ventricular conduction by drug treatment. A clinical use of the device is described elsewhere [19]. As of December, 1966, 30 cases of A-V block had been treated with this new pacemaker, the first of them since February, 1966. Results were constantly very good. All the pacemakers were implanted by using intracavitary electrodes furnished by ELEMA-SCHÖNANDER.[1] Electrode wires are made of flexible, fatigue-resistant stainless steel, polyethylene insulated. Approximate dimensions are given in Fig. 10.

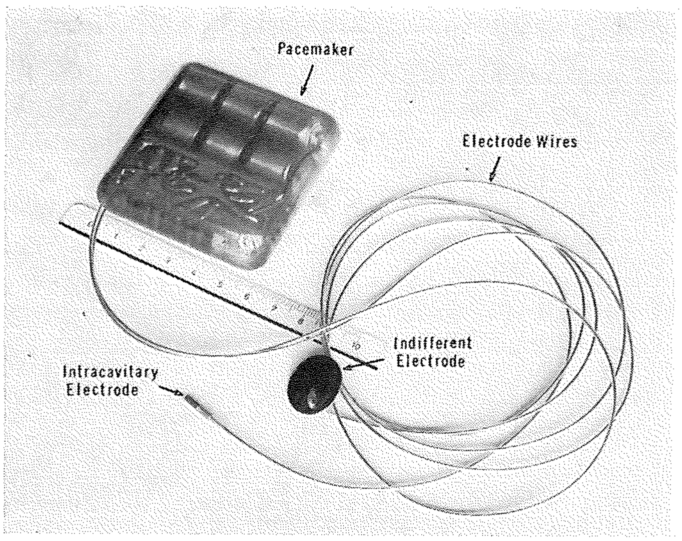

Fig. 10. View of the self-synchronizing cardiac pacemaker realized for subcutaneous implantation with intracavitary electrodes connected.

With the mentioned values of current drain the mean power consumption from an 8-volt battery is about 250 μW, ie., almost the same power required by conventional pacemakers. Hence, if a mercury battery of a volume of 20 cm^3 is used, a theoretical operating time of 30 000 hours without battery replacement is foreseen. Moreover, synchronous operation affords continuous monitoring of proper operation even in the presence of effective A-V conduction; as a consequence, malfunctioning of the pacemaker can be easily detected and appropriate measures taken before artificial pacing is required.

At this point we would note that although we have up to now referred to intracavitary electrodes, the pacemaker described can also be used with intramyocardic electrodes provided that stimulation current is reduced. This reduction can be obtained by either increasing the value of R_{23} or reducing the battery voltage to about 4 V. With the latter solution the whole power consumption drops to about 75 μW, thus increasing pacemaker autonomy.

The photo in Fig. 10 shows a realization of the pacemaker covered with an epoxy resin. As can be seen, pacemaker size is such that subcutaneous implantation is possible.

[1] ELEMA-SCHÖNANDER, Sweden, subcutaneous electrode type EMT 564, intracardial electrode type EMT 588.

Acknowledgment

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References

[1] P. M. Zoll, "Resuscitation of the heart in ventricular standstill by external electric stimulation," *New England J. Med.*, vol. 247, pp. 768–771, November 1952.
[2] S. Bellet et al., "The use of an internal pacemaker in the treatment of cardiac arrest and slow heart rates," *A.M.A. Arch. Int. Med.*, vol. 105, pp. 361–371, March 1960.
[3] W. M. Chardack, "Heart block treated with an implantable pacemaker," *Progr. Cardiovascular Dis.*, vol. 6, pp. 507, 1964.
[4] G. J. Davies, "Artificial cardiac pacemakers for the long-term treatment of heart block," *J. Brit. IRE*, vol. 24, pp. 453–463, 1962.
[5] M. Kahn, et al., "Bridging of interrupted A-V conduction in experimental chronic complete heart block by electronic means," *Am. Heart J.*, vol. 59, pp. 548–559, April 1960.
[6] J. Landegren, "Notes on the use of the artificial pacemaker for complete heart block and Stokes-Adams syndrome," *Acta Chir. Scand.*, vol. 124, pp. 198–204, September 1962.
[7] C. W. Lillehei et al., "Transistor pacemaker for treatment of complete atrioventricular dissociation," *J.A.M.A.*, vol. 172, pp. 2006–2010, April 1960.
[8] W. L. Weirich et al., "Control of complete heart block by use of artificial pacemaker and a myocardial electrode," *Circul. Res.*, vol. 6, pp. 410–415, July 1958.
[9] H. Lagergren and L. Johansson, "Intracardiac stimulation for complete heart block," *Acta Chir. Scand.*, vol. 125, pp. 562–566, June 1963.
[10] P. Zoll et al., "Long-term electric stimulation of the heart for Stokes-Adams disease," *Ann. Surg.*, vol. 154, pp. 330–346, September 1961.
[11] J. B. Schwedel, "Role of the pacemaker," *J. Chron. Dis.*, vol. 18, pp. 891–894, September 1965.
[12] A. Harris et al., "The management of heart block," *Brit. Heart J.*, vol. 27, pp. 469–482; July 1965.
[13] O. F. Muller and S. Bellet, "Treatment of intractable heart failure in the presence of complete atrioventricular heart block by the use of the internal cardiac pacemaker: report of two cases," *New England J. Med.*, vol. 265, pp. 768–772, October 1961.
[14] W. D. Widman et al., "Radiofrequency cardiac pacemakers," *Ann. New York Acad. Sci.*, vol. 111, pp. 992–1006, June 1964.
[15] J. C. Norman, R. Lightwood, and L. D. Abrams, "Surgical treatment of Adams-Stokes syndrome using long-term inductive coupled coil pacemaking," *Ann. Surg.*, vol. 159, pp. 344–361, March 1964.
[16] L. Cammilli, R. Pozzi, and G. Drago, "Remote heart stimulation by radio frequency for permanent rhythm control in the Morgagni-Adams-Stokes syndrome," *Surgery*, vol. 52, pp. 765–776, November 1962.
[17] D. A. Nathan et al., "An implantable synchronous pacemaker for the long term correction of complete heart block," *Am. J. Cardiology*, vol. 11, pp. 362–367, March 1963.
[18] L. Donato, "Discussion remarks on pacemakers," communication at the 1966 Symposium on the Electric Control of the Heart Block, Montecatini, Italy.
[19] L. Donato and F. Denoth, "Selfsynchronizing cardiac pacemaker for treatment of intermittent A-V block," *The Lancet*, July 23, 1966.