## A report on an implantable electronic cardiac pacemaker

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The cardiac pacemaker, although comparatively new, is no longer in an experimental stage. It is now in the armamentarium of medical men and surgeons concerned with treating complete heart-block with Stokes-Adams seizures.

Four or five years ago, when the need for such a device became obvious, several centers started working on different types of pacemakers that were reported almost simultaneously. Senning and Elmqvist<sup>1</sup> were probably the first to develop a permanently implantable electronic pacemaker (1959). Made by the Elema Company in Sweden, it had a passive receiver and an external power source. Chardack and associates<sup>2,3</sup> in Buffalo, Zoll and co-workers<sup>4</sup> in Boston, our group at Maimonides,<sup>5,6</sup> and others<sup>7-9</sup> developed implantable devices based on essentially the same principle. Weirich and associates<sup>10</sup> had previously shown that far less energy is required to stimulate the heart with electrodes implanted in the myocardium than with Zoll's external stimulation method.

Our pacemaker, developed with the General Electric Company, has undergone a number of modifications. The first unit was round, about 2.5 cm. in diameter, and weighed 4 oz. Its components were potted in epoxy resin and the case was of Teflon. Placed in an abdominal pocket, its electrodes were passed through a tunnel to the myocardium of the left ventricle where they were securely embedded. This device was extensively tested in dogs with good results, and we eventually used a similar one in our first clinical case, but it gave us some difficulties.

The latest model has essentially the same components:5 batteries, 2 transistors, 3 resistors, and 1 capacitor (Fig. 1). It has been amply demonstrated that the fewer the components in a device, the higher is its potential for safety and reliability.

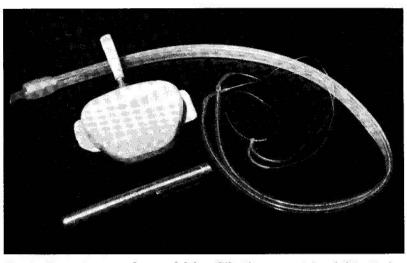
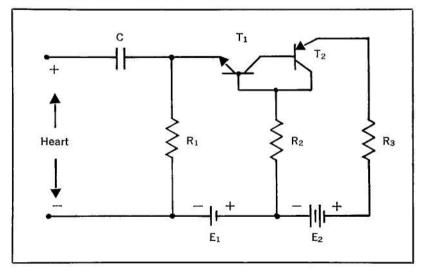


FIG. 1. Current pacemaker model has Silastic case; strip of Silastic-impregnated Dacron mesh facilitates suturing of case to anterior rectus sheath. Note the slip fit for helicable twin electrodes and magnet for external rate adjustment.

The General Electric pacemaker has 6 components as compared with 12 for the Zoll-Electrodyne, 15 for the Chardack-Medtronic, and 52 for the Nathan-Cordis.

The electronic circuit is relatively simple (Fig. 2). The two transistors act as a switch. When the capacitor is discharged, the transistor switch is closed, and the capacitor is charged from batteries E1 and E2, imparting an impulse to the heart. When the capacitor is fully charged, which takes about 2 msec., the transistor switch opens and can no longer conduct current. It takes about 1 second for the capacitor to discharge through R1, thus setting the impulse frequency. The transistors again act as a closed switch and a second stimulus is sent to the

FIG. 2. Electronic circuit of implantable pacemaker



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heart for 2 msec. This pattern is repeated, pacing the heart steadily and reliably.

The electrodes are implanted about 1 cm. apart in an avascular area of the left ventricle. We feel that the operative procedure should be as uncomplicated as possible. On opening the chest cavity at the left fourth intercostal space via the anterior approach, this part of the left ventricular myocardium first presents itself. Furthermore, it is sufficiently thick to ensure against accidentally entering the lumen of the ventricle.

Experience with our first patients revealed that insufficient electrical energy was being delivered to the myocardium for effective stimulation. After electrodes are implanted, it takes some time for the threshold to reach its eventual level. On letting the electrodes "mature" in this fashion for three or four weeks, we found that about 15 microjoules were required to stimulate the heart. No response was obtained below this level and the response was not increased with a higher level. Our original unit was therefore designed to deliver about 20 microjoules. As it turned out, this allowed too slim a margin above the threshold, which varies considerably in different individuals. Later units have delivered about 64 microjoules, a margin of over 300%. Silastic, which has supplanted Teflon for the case, is easier to seal hermetically. The leads have been changed a number of times. In common with the other investigators, we have found wire breakage a persistent and plaguing complication.

Recently, the electrodes have been made of 294 helically wound filaments of stainless steel and 49 helically wound filaments of silver. These provide both longitudinal stretch and reduced kinking. These filaments are encased in silicone rubber with a silicone fluid lubricant to reduce friction within the cable. Breakage has not occurred in personal experience with over 100 such "Helicables."

The output waveshape of the implanted pacemaker has a sharp spike up to about 3.2 volts which subsides rapidly. About 90% of it is over within 2 msec., but it takes about 8 msec. for the voltage to return to zero (Fig. 3).

The pulse rate has been raised from 65 to 70 per minute in recent models, but the pulse time constant remains the same -2 msec., which is sufficient to trigger the myocardium. Data supplied by the battery manufacturer at first led us to expect about 40,000 hours or five years of use. Batteries in most of the units have run out within two and one-half years, however.

An additional feature of the General Electric pacemaker is a small, optional external control circuit, which men usually carry in a pocket and women inside the brassiere. An induction coil from the unit is taped on the abdomen over the implanted pacemaker (Fig. 4) and adjustment of a dial varies its rate anywhere between 70 and 120 pulses per minute. This circuit has proved advantageous in a number of situations. For example, our postoperative patients are paced two or three days at 85

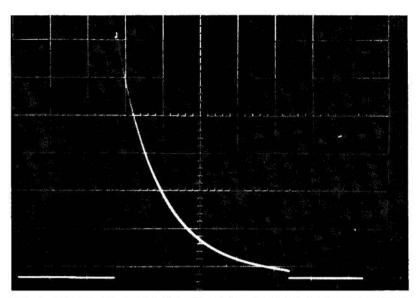
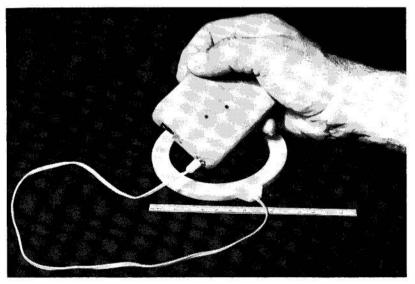


FIG. 3. Waveshape spikes sharply up to about 3.2 volts and subsides rapidly, with 90% of spike over in 2 msec., although voltage does not return to zero for about 8 msec. (abscissa calibration: 2 msec. per square; ordinate calibration; 0.5 volt per square).

to 90 pulses per minute. They appear just as much in need of increased cardiac output as patients undergoing a thoracotomy for different reasons, who respond naturally with a similarly high rate. A number of patients were readmitted after the pacemaker procedure with various intercurrent infections, for example, pneumonia or pyelonephritis, and high temperatures. They responded well to an increased rate while fighting the infection.

In patients with complete heart-block and Stokes-Adams sei-

FIG. 4. External control circuit with induction coil which is placed over implanted unit.



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ndication	
Heart-block, Stokes-Adams seizures	64
Sinus bradycardia, Stokes-Adams seizures	1
Heart-block, congestive heart failure	2
Sinus bradycardia, heart-block	2
Sinus bradycardia, multiple arrhythmias	1
Putcome	
Alive and well	52
Died	18

zures, the mechanism underlying the seizures is commonly ventricular tachycardia, with the risk of ventricular fibrillation rather than ventricular standstill. My feeling, shared by most of the cardiologists of our group, is that the majority of Stokes-Adams sufferers succumb to ventricular fibrillation. At any rate, we are convinced that by raising the cardiac rate it is possible to override intrinsic rhythm and suppress ventricular tachycardia.

Heart-block with Stokes-Adams seizures has been far and away the most common indication for the pacemaker (see table). Among the few other indications, an interesting category is patients with congestive heart failure due to heart-block and a slow rate—a condition that should be relieved by an increased pulse rate. In a three-year period (1961-1964), 18 of 70 patients died; 52 are alive and well.

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