

# A FIXED-RATE RECHARGEABLE CARDIAC PACEMAKER

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*Currently used cardiac pacemakers are quite large and heavy and require replacement on the average of every 22 months. The Applied Physics Laboratory, in conjunction with The Johns Hopkins Medical Institutions, is developing a pacemaker containing a nickel-cadmium cell that can be recharged by magnetic induction through the intact skin. This device has approximately one-fourth the volume of presently used pacemakers and should have a lifetime of at least ten years. When developed and tested, this pacemaker will offer greatly improved therapy for those persons requiring implanted cardiac pacemakers.*

## Introduction

**T**HE PULSE RATE CONTROL MECHANISM (called the "pacemaker") for a normal heart is located in a small region of the right atrium called the sinoatrial node. The electrical stimulus generated there passes around the muscular atrial wall, causing this chamber to contract. The electrical stimulus then passes through a biological relay mechanism, called the atrio-ventricular node, which, after introducing a brief time delay, transmits the signal through specially conducting tissue called the Bundle of His to the ventricles. The arrival of the electrical signal at the ventricles produces contracting or beating of this section of the heart.

As a result of heart disease, the normal electrical conduction through the atrio-ventricular node and/or the Bundle of His can be interrupted. As a result, the patient's heart rhythm will no longer be controlled by the heart's normal pacemaker. However, the patient will not usually die because most hearts have a "back-up mode" where the ventricles will, on their own, beat at a rate between 35 and 45 beats per minute (bpm) in the absence of the normal stimulus.

Although a person will not usually die immediately from this slow heart beat, at best he does not feel well and is very restricted in his physical activities; at worst his kidneys, liver, and other vital organs will fail as a result of insufficient blood flow. An electronic pulse generator which has been given the name "cardiac pacemaker" can be implanted in the body to artificially stimulate the heart to beat at a normal rate.

Early implantable pacing systems used electrodes sewn onto the exterior wall of the heart. This required an open chest operation with considerable hazard to the patient. The electrode leads were routed under the skin and connected to a pulse generator which was buried under the skin, usually in the upper abdomen. The requirement for this major surgery with its attendant high risk was eliminated by the development of an endocardial (inside-the-heart) electrode which could be inserted into the heart through a vein without requiring a major operation. When using an endocardial electrode, the pulse generator would typically be placed in the upper left portion of the chest under the skin and outside the rib cage. In this region a small vein would be entered and a catheter wire inserted. The catheter would then be passed through this vein into the major vein that comes from the left arm, going toward the heart. The catheter would then continue to be extended through the large vein, entering the right side of the heart from above through the superior vena cava. From there, the catheter would be extended through the right atrium, through the tricuspid valve, and finally the electrodes at the end of the catheter would be wedged into the heart muscle at the bottom of the right ventricle. (This is illustrated in Fig. 1.) The catheter would then be tied in place at the vein where it entered the venous system with a permanent suture. The electrical pulses from the pulse generator, transmitted through the insulated catheter wire and emanating from the electrodes firmly wedged against the inner (endocardial) surface of the right ventricle, cause the heart to beat at a rate determined by the

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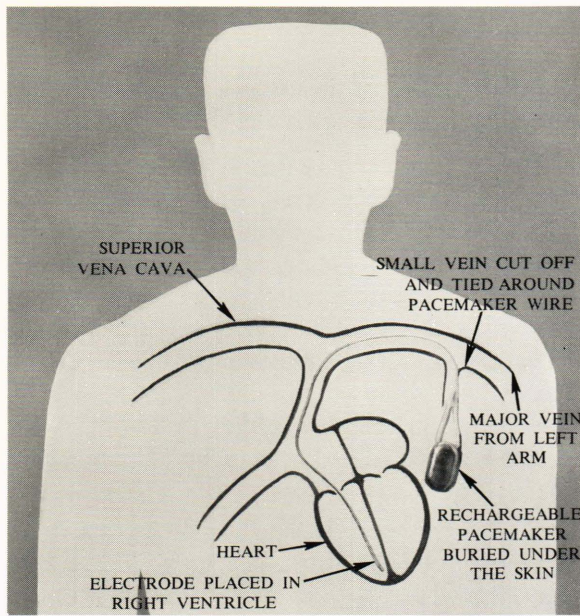


Fig. 1—Typical placement of pacemaker.

pulse generator frequency. It is interesting to note that the tissue that was normally drained by the vein which was cut off finds alternate channels to return blood to the heart.

Early pacemaker applications encountered problems of catheter breakage, especially when the pulse generator was located in the abdominal region. With the trend toward use of endocardial pacemaker catheters, but more importantly, with the development of new alloys and the coil-spring electrode catheter, the problem of electrode breakage has been greatly reduced. Currently available pacemaker electrode catheters are satisfactory for management of pacing problems. There have been essentially no problems of blood clotting around the endocardial catheters.

The major items contributing to the general unsuitability of currently available pacemakers are the power source and the size and weight of the pulse generator.

The present implantable pulse generators are powered by mercury cells. Since these cells can not be recharged, they have a comparatively short life span. Dr. Seymour Furman, of New York's Montefiore Hospital, has made a study over the last six years of 500 patients with implanted pacemakers. On fixed-rate pacemakers, the average lifetime is 22 to 23 months, and on the more commonly used demand type pacemaker, the average lifetime varies from as short as 14 months

with one model to a maximum of 22 months with another.<sup>1</sup>

The largest manufacturer of pulse generators suggests that they be replaced at 18-month intervals in order to avoid added risks involved by sudden end-of-life of the battery. This means that approximately every 18 months a person with an implantable pacemaker must be hospitalized, have the old unit removed by opening the pocket under the skin where the pulse generator was placed, and have a new generator connected to the catheter and sewn into the pocket.

There is some risk of infection in this repeated pulse generator change. This risk is greater than in other surgical procedures because of the unfavorable situation of creating a pocket in between body tissues and putting a foreign body into it. If this pocket with its foreign body does get infected, the only satisfactory way of dealing with it is to completely remove the entire pacing system, including the catheter and pulse generator, and place it in another area of the chest. It is often necessary to allow the original infection to subside before reimplantation; this means that the patient is deprived of the benefit of an implanted pacemaker during this period.

Many patients abhor the thought of such recurring operations. (It is often noted that many cardiac patients are more fearful of surgical procedures than people with normal heart function.) Some patients have refused the benefits of implanted pacing systems because of this dread of recurring surgery. Obviously, any pacing system that would not require re-entering the body after the initial implantation would be of great benefit.

The size and weight of currently available pulse generators is also a problem. In those patients who have thick layers of tissue under the skin, the size is not critical, but in children who need heart pacing as a result of cardiac surgery the current size is not acceptable. There is also a problem with elderly persons whose skin and tissues under the skin are very thin. In some patients the weight of the pulse generator has caused it to slowly slide down between the layers of tissue. This pulls on the catheter and may increase the chance of electrode breakage, and it has even pulled the electrode out of position in the heart with a consequent loss of pacing action.

<sup>1</sup> "Demand Pacers Get a New Rating: Below Expectations," *Medical World News*, Mar. 13, 1970, 15-16.



The limiting factor in reducing the size and weight of the pulse-generator is the power source. No other primary cells available today can appreciably reduce the weight or volume over that required by the mercury cells that are currently used. To lower the battery capacity is highly undesirable because it would result in even a shorter useful life for the pacemaker. Any attempt to add battery capacity would increase volume and weight almost proportionally to the increase in capacity; again this is highly undesirable.

### **Design Goals for a Rechargeable Pacemaker**

From the preceding discussion it is obvious that a major improvement in cardiac pacing systems could be achieved by incorporating an energy storage system that would not have to be replaced every few years and that would be much smaller and lighter. A small, long-life secondary (i.e. rechargeable) battery would provide such a source. Ideally, it should be capable of recharging without mechanically penetrating the skin. This then could provide a permanently implantable pacing system that would eliminate the disadvantages of currently available systems. Penetrating the skin is totally unacceptable because it could result in infection that would be carried along the catheter into the heart.

Experience of the APL Space Department with rechargeable nickel-cadmium (Ni-Cd) satellite batteries suggested that such cells could provide the type of energy source required by an implanted pacemaker. Hermetically sealed Ni-Cd cells have provided long-life, light-weight, energy storage systems for many space applications. Also the electronic component packaging techniques developed for spacecraft could contribute to decrease the size and weight of the pulse generator.

The development of a pulse generator using a rechargeable Ni-Cd battery was initiated with the following design goals:

1. Rechargeable by magnetic induction through the intact skin.
2. Desired life of ten years (with five years as the minimum acceptable life).
3. Smallest possible size and weight.
4. Use of a single Ni-Cd cell as the energy storage system.
5. Minimum time to recharge two hours or less once each week.

6. High reliability and fail-safe circuit design.

### **Application of Nickel-Cadmium Cells for the Rechargeable Pacemaker**

In designing the pacemaker, the first consideration was given to selecting the rechargeable cell. The advent of earth satellites resulted in the development of exceedingly small and reliable, rechargeable electrochemical cells. The greatest success to date has been achieved with hermetically sealed, nickel-cadmium cells. The performance of rechargeable batteries in orbiting satellites designed by APL provided an indication that it was possible to achieve the high reliability required for a pacemaker.

Since June 1963, 18 satellites designed by APL have been placed in orbit containing on the average 10 Ni-Cd cells per satellite. In this period of time there has not been a failure of any one of these 180 cells which was not a direct result of a solar cell power generation failure.

Cell life is strongly dependent on the number of cycles of charge and discharge and on the depth of discharge. Figure 2 shows some experimental data on cell life for Ni-Cd cells as a function of temperature and the number of charge-discharge cycles. APL satellites typically have depth of discharge of 13 percent or lower at an average temperature of 60°F.

Typically, the cells on orbiting satellites are recharged 100 times each week. As a result of the temperature and low depth of discharge, the cycles to failure is such a large number that it does not appear in any curve of Fig. 2.

A 25 percent or less depth of discharge for the Ni-Cd cell is anticipated for the rechargeable pacemakers described. The expected charge cycle will be a two-hour charge once each week. This provides 52 cycles per year, which is equivalent in one year to less than four days of cycling life on an orbiting satellite. Using Fig. 2 at 100°F, and even at 25 percent depth of discharge, 4300 cycles can be expected before cell failure; this number of cycles would be encountered in 82.8 years of pacemaker operation. From these data and from actual flight experience with APL orbiting satellites, one can envision that the useful life of an implantable pacemaker should not be limited by the cycle life of the nickel-cadmium cell.



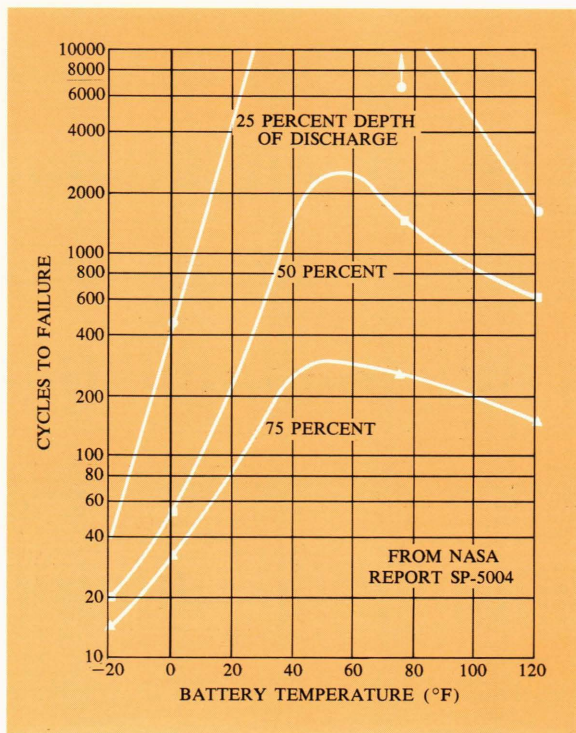


Fig. 2—Nickel-cadmium cell failures as a function of depth of discharge and temperature (12 ampere-hour cells).

For the APL pacemaker it was decided to use a single-cell battery. This approach provides the highest ratio of active chemical materials volume to case volume and also a higher degree of reliability compared to a multicell design. Another important advantage is that in a multicell design, complete discharge can result in permanent damage to that cell in the series string that had the least capacity. With a single cell, even though it might accidentally be completely discharged, it can be readily recharged with no damage whatsoever.

The first cell that was tried with the pacemaker was a commercially available type (approximately \$1.50 each) which was pressure-sealed with plastic but not hermetically sealed. This cell performed satisfactorily at body temperature and served to confirm the concept that the Ni-Cd cell could be operated at body temperature. However, it was felt that in time the electrolyte would leak through the plastic seal. Therefore, it was decided to develop a hermetically sealed pacemaker cell similar to those that have been employed successfully on orbiting satellites. The result of this

development is the cell shown on the left in Fig. 3. The same company that had successfully manufactured satellite cells was chosen to make these hermetically sealed cells (at a cost of approximately \$500 each for the first 25). It was an unfortunate circumstance that just at this time the manufacturer was unsuccessful in producing space cells; also the pacemaker cells began to fail after approximately six months in tests. This manufacturer has subsequently made some more pacemaker cells that appear to operate satisfactorily and these will be on test starting in March 1970. To better guarantee that a good nickel-cadmium cell would be available, another cell manufacturer, who is currently providing successful batteries for APL satellites, is manufacturing 25 additional cells which, hopefully, will operate satisfactorily for pacemaker application. The first of these cells will be delivered in May 1970.

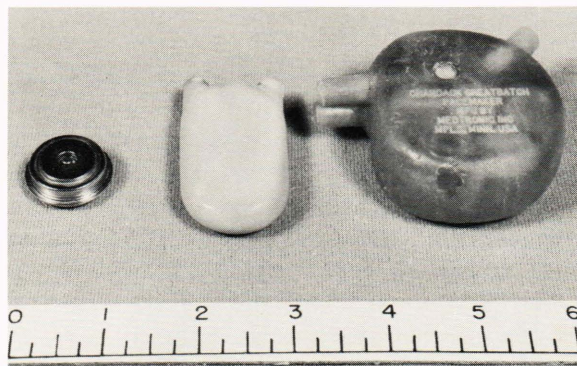


Fig. 3—Photograph showing the pacemaker nickel-cadmium cell and a comparison between the APL and commercially available pacemakers (the scale is in inches).

### Pulse Generator Development

At the outset of this work it was decided to utilize an existing catheter to conduct the electrical signal to the heart. The effort at APL was therefore concentrated on the development of a pulse generator that would satisfy all the design goals listed above. The circuit of Fig. 4 was developed and tested for this purpose. As seen in Fig. 4, the external charger provides a 25 kHz current into the charging head which is inductively coupled through the skin into the pulse generator's input transformer. There it is full wave rectified, filtered, and fed through a Field Effect Transistor (FET) Current Limiter which limits



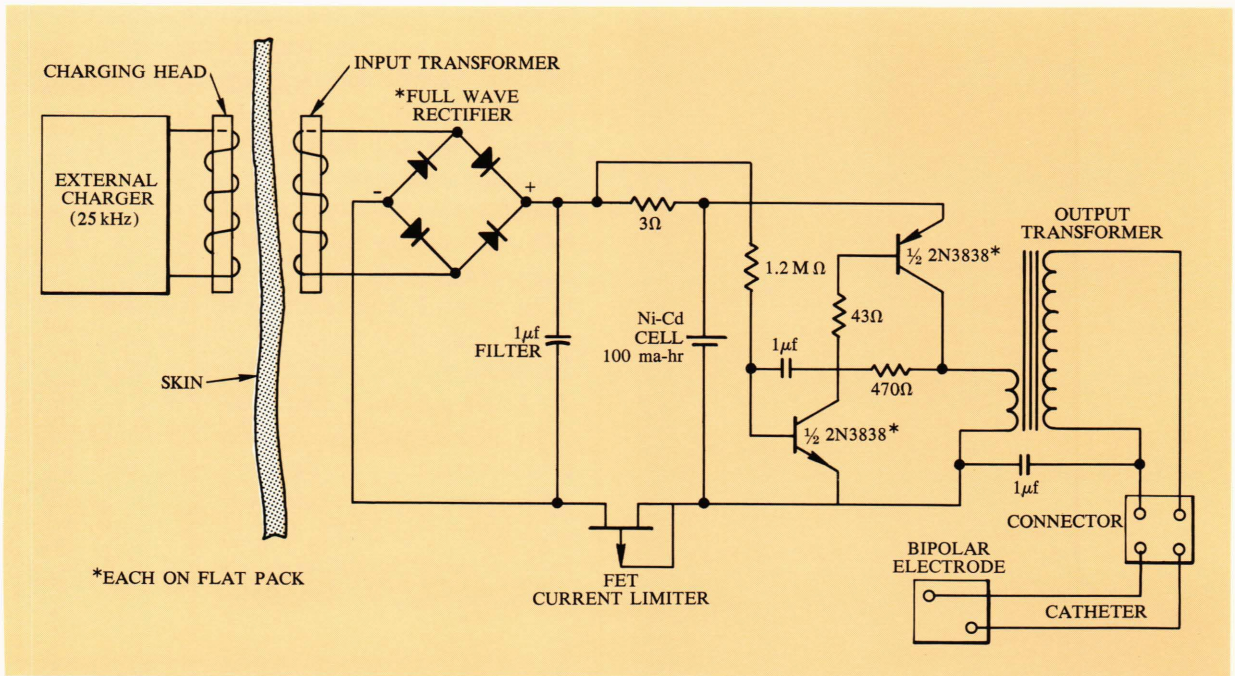


Fig. 4—Circuit diagram for rechargeable fixed-rate pacemaker.

the battery charge current to 40 ma. The purpose of limiting the current to 40 ma is that some patients who are told two hours of charging a week is adequate, will instead charge 12 hours a day. By limiting the battery charge current to 40 ma, the cell can be continuously charged with no damage to the cell or the pacemaker.

The Ni-Cd cell provides the electric power to run a pulsing circuit that provides a positive-going 1 ms pulse at a rate of 72 bpm into the heart. The wave shape into the heart is shown in Fig. 5.

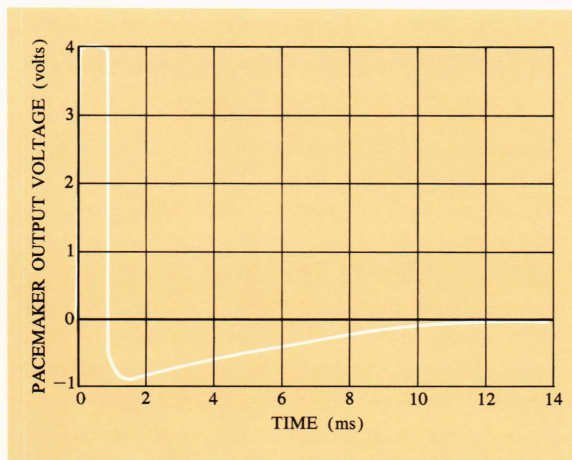


Fig. 5—Pulse waveform of rechargeable pacemaker.

The initial positive-going pulse triggers the heart. It will be noted in Fig. 5 that the negative-going pulse has approximately the same area under its curve as does the positive pulse. This is highly desirable since it accomplishes the desired triggering of the heart while preventing any net ion flow in the blood near the electrodes.

The output transformer shown in Fig. 4 is used to increase the 1.25 nominal voltage of the nickel-cadmium cell to 4.0 volts, which is more satisfactory for triggering the heart.

Figure 6 is a photograph of a rechargeable fixed-rate pacemaker before its final exterior plastic coating is added. This figure shows the input transformer which is used to receive the energy from the External Charger. After considerable study it was determined that a charging frequency of 25 kHz was well suited for the purpose of transmitting energy through the skin. At a very much higher frequency than 25 kHz, there is attenuation through the body's conducting tissues. At lower frequencies the coupling from the external source of energy into the input transformer was less efficient. At the 25 kHz frequency selected there is no detectable heating effect even though the charging head is placed directly on the skin for extended periods of time.

It should be noted that the electronic com-



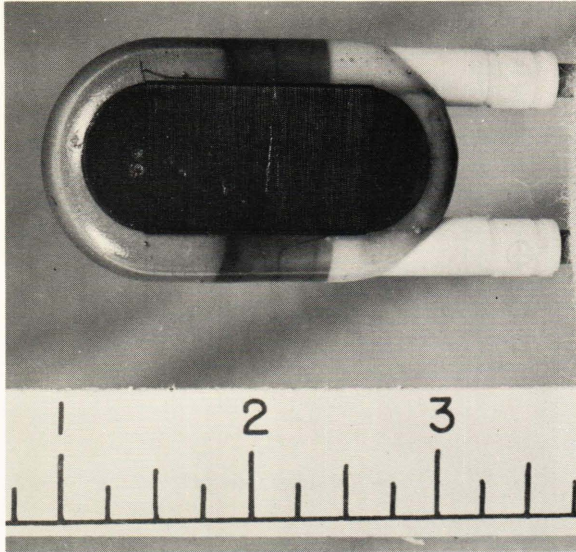


Fig. 6—Rechargeable pacemaker showing input transformer (the scale is in inches).

ponents, except for the input transformer, are contained within a hermetically sealed gold case. The requirement for a hermetic seal for the pulse generator is unique for the APL-developed pacemaker. On the currently used pacemakers the primary mercury battery is contained with the other electronic components in a hard plastic (see Fig. 3). It is a characteristic of the encapsulation compounds that are used that, within a few years, body fluids diffuse through the plastic and can have a corrosive effect on the electronic components. Fortunately for pacemakers the energy contained in the battery is dissipated before the electronics are damaged by body fluids diffusing through the plastic. To design a pacemaker that will last 10 years or longer it is required to prevent body fluids from reaching the electronic components contained therein. The APL pacemaker accomplished this by gold-plating the plastic and using glass-Kovar seals for making electrical connection to the catheter and to the input transformer.

In the photograph of Fig. 3 the size comparison between the most frequently used commercial unit and the APL pacemaker can be seen. One of the rechargeable cells is also shown in this figure. The reduction in size that has been obtained by recharging is clearly shown. The table gives a comparison of the size, weight, and expected operating life of the two pacemakers shown in Fig. 3.

	Currently Used Pacemaker	APL Pacemaker
Volume	88 cm <sup>3</sup>	22 cm <sup>3</sup>
Weight	178 gm	63 gm
Expected Lifetime	22 months	120 months

To guarantee that the pulse generator could be charged successfully even when the patient had a very thick skin and subcutaneous tissue, the criterion was established that the saturation charge level of 40 ma should be obtained at a separation distance of at least 1.0 inch between the charging head and the input transformer. An external charger was developed that provided the required 40 ma at a separation distance of 1.2 inches as shown in Fig. 7. The fall-off in current at a distance of less than  $\frac{3}{4}$  inch is a result of heating of

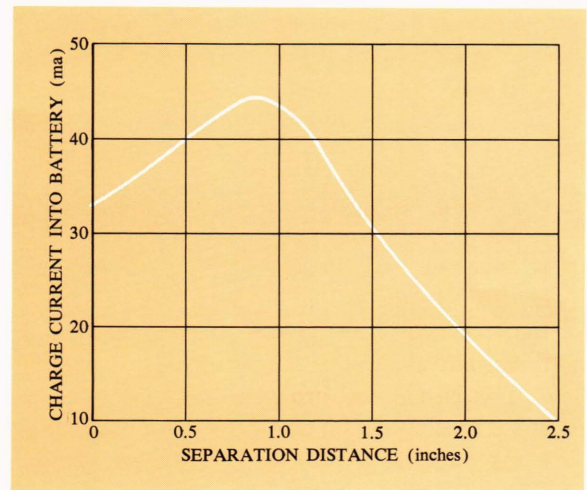


Fig. 7—Battery charge current as a function of separation distance between charging head and input transformer.

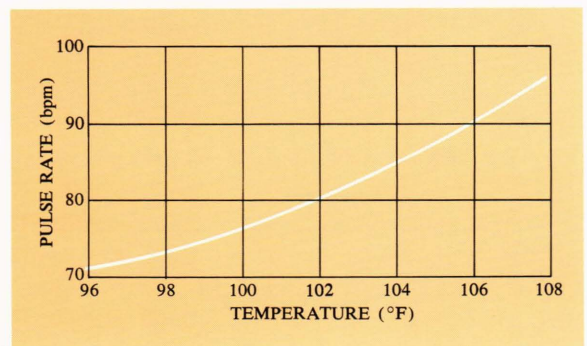


Fig. 8—Variation in pulse rate with pacemaker temperature.



the FET Current Limiter causing an increase in its ohmic resistance.

An interesting characteristic of the pulse generator is its change in pulse rate depending on the patient's temperature. If a person with a normal heart develops a fever, his pulse rate will increase. This increase is one of the body's mechanisms to help alleviate the illness that is causing the rise in body temperature. The rechargeable pacemaker has been designed (as can be seen in Fig. 8) to provide a similar increase in pulse rate when the body temperature increases.

### Pacemaker Telemetry

It is desirable to monitor the nickel-cadmium cell performance without making physical contact with the implanted pacemaker. The telemetry system that was developed utilizes small variations in the patient's pulse rate to measure the desired parameters. Figure 9 indicates the variation in pulse rate with battery voltage. The normal operating range for battery voltage is from 1.35 volts immediately after being charged to 1.2 volts after one week of discharge. During this period the pulse rate will decrease from approximately 76 to approximately 74 bpm. If a patient observes a rate of 70 bpm or less in less than one week after charging, it is indicative of potential cell failure and could be cause for pacemaker replacement.

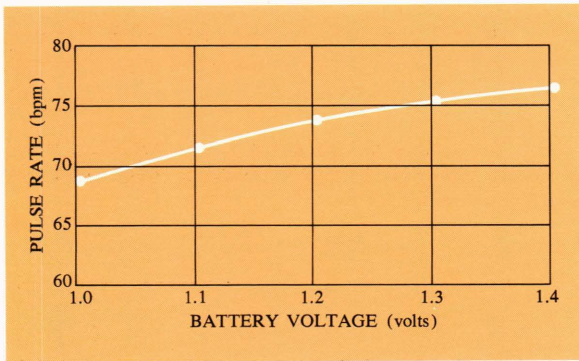


Fig. 9—Pulse rate dependence on battery voltage.

The circuit of Fig. 4 was designed so that the presence of charge current into the battery would result in an increase in pulse rate. Figure 10 shows the change in pulse rate with charging current that is obtained with the fixed-rate rechargeable pacemaker. When the patient has the charging head properly positioned and the external charger

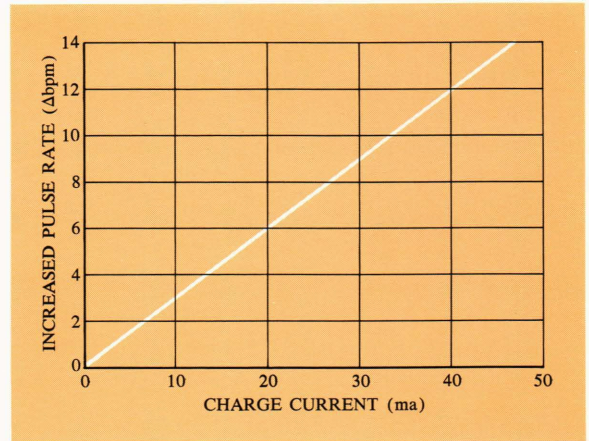


Fig. 10—Change in pulse rate with charge current.

turned on, he will observe a change in pulse rate of approximately 12 bpm at a charge current of 40 ma. By this means he will know that his pacemaker battery is being properly recharged.

Figure 11 indicates the variation in pulse rate that is expected during the one week charge-discharge cycle. By this telemetry system, not only can the patient qualitatively determine the performance of his implanted pacemaker, but also the biomedical engineer can qualitatively determine the performance capability of the implanted unit.

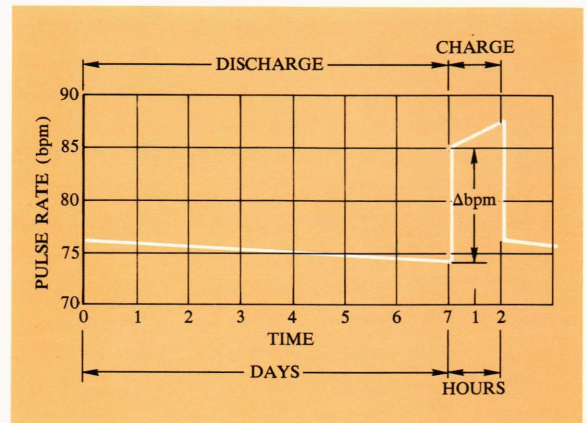


Fig. 11—Pulse rate telemetry of rechargeable pacemaker.

### Advantages of the Fixed-Rate, Rechargeable Pacemaker System

The advantages of the fixed-rate, rechargeable pacemaker system are summarized below:

1. There are no life-limiting components; there-



fore, periodic replacement of the pulse generator is not required.

2. By precluding the necessity for repeated implantations of pulse generators, the danger of infection in the avascular pocket is virtually eliminated.

3. The long-term cost to the patient is drastically reduced both in regard to the expense of the pulse generators and the cost of several operations.

4. There are patients who refuse to have a pacemaker implanted because they must undergo an operation every 18 to 24 months, but they would more readily accept the surgical procedure for a one-time implantation of the rechargeable pacemaker system.

5. The patient will not suffer the psychological disadvantage of knowing he will surely be operated on at comparatively frequent intervals as is the case with present pulse generators.

6. Once a conventional mercury cell pulse generator is fabricated, it starts to wear out, thereby limiting useful operating life in the patient. The rechargeable pacemaker has unlimited shelf life. It can be stored for years if necessary with no maintenance and charged at any time within a few weeks to a few hours prior to implantation in the patient.

7. The fact that the rechargeable device does not begin to dissipate its operating life as soon as the battery is connected means that extensive testing of the completed device can be performed prior to human implantation. Therefore, if there are any early failures of the pulse generator (termed "infant mortality" by the reliability engineer) they could be detected before the device is installed in a patient. Also, these early tests can be performed without detectably reducing the operational life of the device when implanted in the patient.

8. The fact that the pulse rate decreases as the cell becomes discharged prevents the possibility of "pacemaker high-frequency runaway" which has caused the death of several patients.<sup>2</sup>

9. The output transformer shown in Fig. 4 completely isolates the voltage generating sections of the pulse generator from the catheter and therefore eliminates any possibility that a circuit mal-

function could cause a steady DC voltage to be applied to the heart. This eliminates the possibility of ventricular fibrillation due to the presence of a steadily applied voltage.

10. The small size of the unit makes it convenient to place it in small children as well as adults whose skin and subcutaneous tissue are very thin. In normal adults its small size offers greater convenience in the surgical procedure. The light weight of the unit reduces the possibility that it will descend in the subcutaneous tissue and cause withdrawal of the catheter from the right ventricle as has been experienced with some heavier pulse generators.

11. The low internal impedance of the nickel-cadmium obviates the necessity for electrolytic condensers which *are* required for the higher internal resistance offered by mercury cells. These capacitors are a comparatively unreliable electronic component.

## Experimental Results

The rechargeable fixed-rate pacemaker has been tested in the laboratory and has been implanted in three dogs. Each of these dogs had heart block artificially induced so that they required a pacemaker to maintain a reasonably high pulse rate. To date there have been no electronic component failures of any of these units. However, in all units except one fabricated in February 1970 the nickel-cadmium cell has failed. As previously stated, new cells are being manufactured that should perform satisfactorily in a pacemaker application. The tests with laboratory dogs did successfully prove out all other aspects of the rechargeable pacemaker system, including repeated recharging through the intact skin.

## Acknowledgment

The work on the pacemaker required the advice and skill of a considerable number of individuals both at the Applied Physics Laboratory and elsewhere. Among those who contributed at the Laboratory are: G. R. Seylar, original circuit design; J. D. Steinberg, mechanical design; D. R. Fisher, encapsulation; F. J. Porter, Jr. and G. F. Sweitzer, electronic fabrication; and A. U. Alexander, W. J. Hays G. A. Hillman and R. J. Evans, electroplating. At the Baltimore City Hospital, the pacemakers were surgically inserted by Dr. J. W. Love with the assistance of Miss S. S. Mills.

<sup>2</sup> H. Siddons and E. Sowton, "Cardiac Pacemakers," Springfield, Ill., Charles C. Thomas, 1967, 104, 110-111.