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Balancing the Failure Modes in the Electronic Circuit of a Cardiac Pacemaker: A Decision Analysis

BOAZ RONEN*, JOSEPH S. PLISKIN†‡ and SHLOMO FELDMAN§
*ELTA Electronics Industries Ltd (a subsidiary of Israel Aircraft Industries Ltd), †Department of Industrial Engineering and Management, Ben-Gurion Univerisity of the Negev and §Heart Institute, Chaim Sheba Medical Center, Tel-Hashomer and Sackler School of Medicine, Tel-Aviv University

Cardiac pacemaker malfunctions are of continuous concern to the medical profession as well as to the electronics industry. Certain failures in cardiac pacemaker performance are critical and can result in patient deaths. Cardiac pacemakers are vulnerable to certain malfunctions in the electrode, batteries and the electronic circuit. This paper focuses on failures and reliability of the electronic circuit and how they affect its choice and design. The paper discusses the issues of balancing the various failure modes by considering both failure rates and failure outcomes.

As the choice of an appropriate pacemaker is a decision problem under conditions of uncertainty, we employ decision analysis as the analytical and conceptual framework. Use of utility theory enables a systematic quantitative evaluation of such seeming intangibles as the various failure outcomes. Probabilities are assessed using specific engineering and reliability literature. The method is demonstrated on a choice problem between two specific electronic circuit designs.

The methodology can be useful in designing the electronic circuit to meet certain reliability specifications, deciding whether or not to introduce redundancy, decisions affecting components and technology, and establishing minimal reliability standards, with regard not only to cardiac pacemakers but to other electronics as well.

INTRODUCTION

AN ELECTRONIC CARDIAC PACEMAKER is a device that artificially controls the pulse rate of the heart. When the intrinsic pacemaker of the heart cannot provide adequate spontaneous rhythm, there may be a need to implant an electronic pacemaker. It provides electronic stimulation through a special electrode (transvenous or myocardial) that connects the pacemaker to the heart.

Most earlier versions of pacemakers generated a constant electronic stimulation. The newer models provide stimulation 'on demand'. If the intrinsic pacemaker of the heart can function to some degree on its own, the tendency is to let it do so (while the implanted pacemaker 'rests') and to call for the electronic pacemaker stimulation when the intrinsic pace is inadequate. Today's pacemakers have reached a level of sophistication where microcircuit chip construction allows for external reprogramming and telemetry.

Cardiac pacemakers are vulnerable to malfunctions in the electrode, batteries and electronic circuit, and pacemaker failures can also occur owing to ineffective sensing (in demand pacemakers) and infection. This paper will focus on the design phase of the pacemaker and in choices among alternative electronic designs. We shall therefore concentrate on failures and reliability of the electronic circuit. The more general problem of choosing among several pacemakers where all of the above failures are considered is discussed elsewhere.[1]

Cardiac pacemaker malfunctions are of continuous concern to the medical profession as well as to the electronics industries. Certain failures in pacemaker performance are critical and can result in patient deaths. This has resulted in strict governmental standards (in the U.S.A.) to preserve appropriate reliability on the part of pacemaker manufacturers. The highly sophisticated nature of today's pacemakers provides a strong incentive to

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‡Parts of this work were performed while the author was with the School of Management, Boston University and the Center for the Analysis of Health Practices, Harvard School of Public Health.

constantly evaluate their performance and failures. Despite the strict standards issued by the Federal Food and Drug Administration, there still exist problems with several manufacturers.[2,3]

Of 123,000 pacemakers implanted from 1973 to 1975, 22,300 units were labelled as suspicious for malfunctions. All pacemakers must be periodically checked to ensure appropriate pulse-generating frequency. Thousands of patients had to undergo additional surgery to replace defective pacemakers, thus incurring additional costs, risks and inconvenience.

One of the main problems in pacemaker reliability research is failure definition. Every manufacturer, research team and medical institution seems to define failures differently, reflecting their own point of view and interests. This paper tries to define all failure modes clearly and in a unified manner.

Some failure modes are more frequent than others; some have more serious implications for the patient. This paper discusses the issues of balancing the various failure modes by considering both failure rates and failure outcomes. As the choice of an appropriate pacemaker is a decision problem under conditions of uncertainty, we employ decision analysis as the analytical and conceptual framework.[4] Use of utility theory enables a systematic quantitative evaluation of such seeming intangibles as the various failure outcomes.

The methodology presented in this paper can be useful in designing the electronic circuit, deciding to introduce redundancy, helping physicians choose among several pacemakers, and establishing a minimal reliability standard for cardiac pacemakers. The methodology presented allows for a different approach to reliability evaluation in general, especially to systems where failure outcomes are not easily quantifiable.[5]

FAILURES IN THE ELECTRONIC CIRCUIT

A failure in the electronic circuit usually requires replacement of the defective pacemaker with a new one. Several failure modes are possible:

(1) *Runaway pulse*—the pulse frequency of the circuit is faster than originally planned. If the resulting heart rate is far beyond physiologic heart rate, the implications for the patient are very critical and can lead to death.
(2) *Slow pulse*—the pulse frequency is slower than originally designed. The source of this failure can either be the electronic circuit or a reduction in battery voltage. We shall concentrate on the former, where the malfunction is usually caused by a defective component. In most cases, the implications for the patient are not severe. If the failure is detected in time, the pacemaker can simply be replaced without too high a risk for the patient.
(3) *No output*—the pacemaker ceases to provide electronic stimulation.
(4) *Intermittent pulse*—the pacemaker is not properly functioning on a continuous basis. This failure is rare and will not be categorized separately.

Failures due to the electrode, infection or ineffective sensing (in a demand pacemaker) will not be considered in this paper as we are addressing only the electronic circuit. As mentioned earlier, these failures were considered in a broader analysis.[1]

The specific categories we shall consider in the analysis are presented in Table 1. We

TABLE 1. FAILURE MODES AND POSSIBLE OUTCOMES

Failure No.	Failure mode	Outcome
1	No pulse	Pacemaker not functioning at all
2	Exit in high (HI)	Constant flow of current to heart, possible fibrilation
3	Slow pulse	Pacemaker only partially functioning
4	Runaway pulse	Pacemaker working too fast
5	Intermittent pulse	Pace changes, interruptions
6	OK	Pacemaker is functioning well

shall actually not relate to the 'intermittent pulse' failure because of its rarity. In the related study,[1] of the 120 failing pacemakers, not a single 'intermittent' failure has been detected.

THE DECISION PROBLEM

The focus of this paper is the choice problem among alternative designs of the electronic circuit of a cardiac pacemaker. The following reasonable assumptions will underly the analysis:

(1) At the design stage there are at least two alternatives (otherwise there is no choice problem).
(2) There are no cost differences among the various alternatives (hence the cost attribute is not relevant).
(3) The reliability of the electronic circuit is determined only by the components (although reliability can be influenced by manufacturing and packaging techniques[5]).

The choice problem enables the decision maker to decide on a specific design but not to control for the actual type of failure whose probability distribution represents the underlying uncertainty in the decision process. Before proceeding with the analysis, we must clarify the issue of whose decision problem we are considering? Is it the designer's, the physician's, the hospital's, or perhaps the patient's? At a first glance we may be tempted to think of the designer as the decision maker regarding the choice of a preferred design. In actuality, it is the cardiologist who chooses one pacemaker over another, and it is his or her subjective preferences that are considered in the choice problem. In theory, it is the patients who must make the choice since the various failure outcomes affect them directly. Because patients may not comprehend the implications of the various end consequences resulting from different failures, we may want to think of the patient-physician team as the actual decision maker. In many cases, though, patients delegate complete authority to the physician to act on their behalf, reflecting their (the patients') best interests. On this premise we decided to use the preferences of the cardiologist involved in this study (S.F.), knowing that other cardiologists may express a different preference pattern, resulting in different choices of pacemakers. An underlying premise for any physician's preferences is that these preferences reflect what the physician believes is best for the patient.

For our analysis we have decided to combine failure modes 1 and 3 into a combined category called 'no pulse' because failure 1 is the limiting case for failure 3 as the frequency approaches zero. The two modes are combined because the available data relate to extreme cases (i.e. 'on', 'off' situations).[6] Also, as far as medical outcomes are concerned, these two failure modes can be similarly detected and have similar implications for the patient.

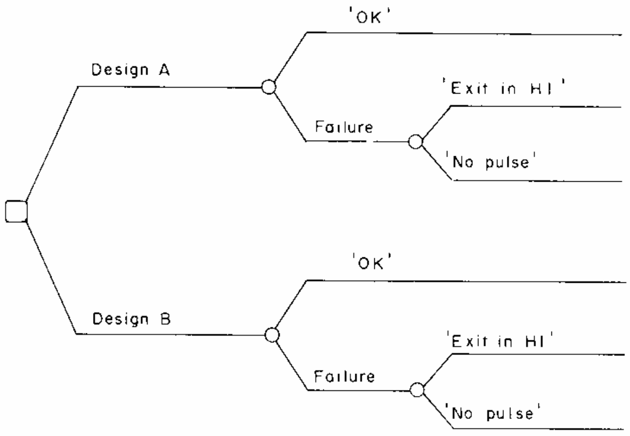

FIG. 1. *Simplified decision tree.*

Actually, the patient is rarely in a situation where there is an absolute constant dependence on the pacemaker. The heart functions to some degree, and the pacemaker is there for 'back-up' purposes. Hence, there is little differentiation between these two failure modes. Similarly, failure 2 is the limiting case for failure 4, and they too will be combined into a single category, 'exit in HI'. This failure type implies a constant output of electronic current to the heart and can result in fibrilation.

The decision tree of Figure 1 depicts the simplified decision problem after some of the failure modes have been combined as previously discussed. Note that there are two levels of uncertainty: first for whether a failure occurred at all or not, and then, given that a failure had occurred, there is a chance node for the actual failure mode. The two chance nodes for each of the alternatives can be combined into one, but the representation of Figure 1 is more convenient in terms of the probabilities that need to be assessed.

UTILITY ASSESSMENT

In the representation of Figure 1, there are only three possible outcomes relating to an 'OK' state, 'exit in HI' and 'no pulse'. The 'best' outcome as far as the patient is concerned is obviously 'OK', and the worst is 'exit in HI'. Once the outcomes have been ranked, we can proceed as follows. Two utility values can be assigned arbitrarily. That sets the origin and unit of measurement. It is convenient to set the utility value of the best outcome as 1 and worst as 0. Hence $U(\mathrm{OK}) = 1$, $U(\text{exit in HI}) = 0$. The classical way of assessing the utility of the intermediate outcome, 'no pulse', is to consider the following choice problem: you can use a pacemaker which you know for certain is going to have a 'no pulse' failure, or you could use a pacemaker which has a probability p of yielding an 'exit in HI' failure and a complementary probability $1\text{-}p$ of being 'OK'. Naturally, if $p = 1$ the choice would be for the pacemaker with the 'no pulse' failure. If $p = 0$ the other pacemaker would be preferred. There is some intermediate value p_0 for which the decision maker has a difficult time deciding (i.e. he is indifferent). If so, the utility of the two choices will be the same. The utility of a gamble or chance node is simply the expected value of the utilities of the individual outcomes.[4] The indifference implies

$$U(\text{no pulse}) = p_0 U(\text{exit in HI}) + (1 - p_0)\, U(\mathrm{OK}),$$

but $U(\mathrm{OK}) = 1$, $U(\text{exit in HI}) = 0$, hence $U(\text{no pulse}) = 1 - p_0$.

As posed above, the choice problem is somewhat unrealistic, and cardiologists find it difficult to think of such hypothetical situations. We revised the approach and used the following choice problem. You are presented with two batches of 1000 pacemakers each. One batch contains 999 defect-free pacemakers and one pacemaker having a 'no pulse' failure. The other batch contains one pacemaker with an 'exit in HI' failure and the rest 'OK'. Which batch would you rather work with? This choice problem is the realistic one faced by the cardiologists and/or the designers. When preferring one design over another, they are in fact choosing one probability distribution over another. Every reasonably-sized ordered batch will contain some defective pacemakers, which will eventually be implanted in patients.

Since an 'exit in HI' failure is more severe, most decision makers would choose to work with the first batch (A). But what if batch A contained two defective pacemakers with 'no pulse', or 10, or 20? The choice is no longer obvious. Different decision makers (cardiologists, designers) will exhibit different preference patterns. In general, if the decision maker is indifferent between having a proportion p_A of 'no pulse' defects and having a proportion p_B of 'exit in HI' defects, we can calculate the utility of 'no pulse'. Indifference between the two gambles implies equal expected utility values for the two choices, hence:

$$p_A\, U(\text{no pulse}) + (1 - p_A) U(\mathrm{OK}) = p_B\, U(\text{exit in HI}) + (1 - p_B)\, U(\mathrm{OK}).$$

With $U(\text{OK}) = 1$ and $U(\text{exit in HI}) = 0$, this reduces to

$$p_A U(\text{no pulse}) + (1 - p_A) = 1 - p_B,$$

or

$$U(\text{no pulse}) = \frac{p_A - p_B}{p_A}.$$

The cardiologist involved in this study was indifferent between working with batch A containing 50 'no pulse' pacemakers (and 950 'OK') and batch B containing 1 'exit in HI' pacemaker. We then have

$$p_A = 0.050 \text{ and } p_B = 0.001,$$

yielding

$$U(\text{no pulse}) = \frac{0.050 - 0.001}{0.050} = 0.98.$$

As this exhibited preference is highly subjective, other decision makers are not expected to have the same utility structure.

If we wish to consider additional intermediate outcomes, we can assess their utilities in a similar manner. The implications of the obtained utility value will be further discussed in the sensitivity analysis section. Again, it should be noted that this 'batch' approach of eliciting utilities was the only one we found meaningful for the cardiologist.

PROBABILITY ASSESSMENTS

Once we have utility values for all outcomes, we must weight them according to the likelihood of realizing each of the outcomes.

The failure rates can be calculated using the *Military Standardization Handbook 217C*,[6] and the conditional probabilities needed for the second level of the chance nodes of Figure 1 can be obtained from the *Reliability Prediction Notebook*.[7] The calculations involve the following assumptions:

(1) The probability of two or more independent failures in different components occurring simultaneously is negligible.
(2) Components' designations that do not appear on the electronic circuit schemes are evaluated by engineering judgments.
(3) Every component can fail in one of two ways: open circuit or short circuit.
(4) The failure occurrence (open or short circuit) of every component is Poisson with rate λP, where λ is obtained from *MILHDBK 217C*,[6] Table 2.1.7-3, and P from the *Reliability Prediction Notebook*.[7]
(5) The 'no pulse' and 'exit in HI' failure rates are calculated as follows:
    (a) The effect of every component on circuit output will be checked. It will be determined whether the output is 'no pulse', 'exit in HI' or 'OK'.
    (b) The failure rate, λP, will be calculated for every state.
    (c) The effect of a short circuit in a component on circuit output will be determined.
    (d) The effect of a short or open circuit on all circuit components will be determined.
    (e) The 'no pulse' rate will be calculated as the sum of the λPs of the components and states yielding a 'no pulse' outcome, similarly for the 'exit in HI' rate.

The preferred circuit design can now be determined by calculating the expected utility for each alternative and choosing the one yielding the highest expected utility. An actual example will best demonstrate the procedure.

AN EXAMPLE

Consider the two alternative electronic designs of cardiac pacemakers taken from the

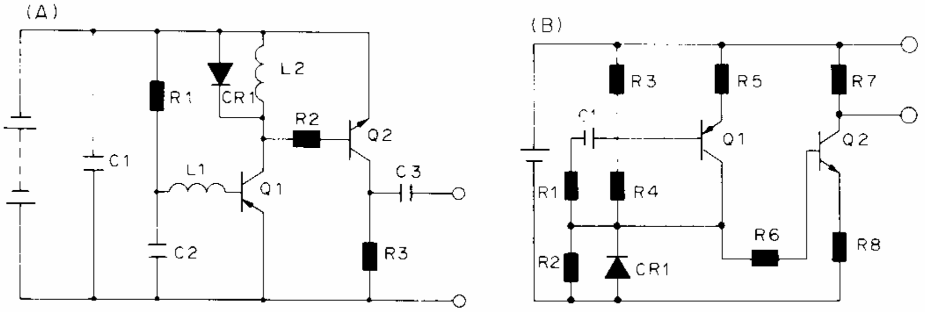

FIG. 2. *Electronic schemes for two pacemakers.* (A) *Pacemaker A*; (B) *Pacemaker B.*

literature,[8] as they are presented in Figures 2A and 2B. These two designs were readily available, which is not the case in general. Also, they represent a rather old generation of pacemakers. Current pacemaker designs are generated by computerized methods using large-scale or very large-scale integration circuits. This enables immediate determination of failure modes as well as probabilities of failure. The designs used in our example facilitate a good demonstration of the decision analytic approach. Today's technology makes it easier to use this approach, and hence enhances its value.

At a first glance, pacemaker A (Figure 2A) seems to have more components that render it less reliable, hence a higher failure rate. On the other hand, it contains a capacitor at the exit, thus reducing the probability for the critical outcome 'exit in HI'. Pacemaker B (Figure 2B) is simpler in structure, and hence has an overall lower failure rate. But it has a higher conditional probability of the 'exit in HI' failure.

The calculations yielded:

for Pacemaker A:

$$\lambda P_{\text{no pulse}} = 2.6 \times 10^{-8} \text{ failures/hour}$$
$$\lambda P_{\text{exit in HI}} = 2.4 \times 10^{-9} \text{ failures/hour}$$
$$\lambda P_{\text{Total}} = \lambda P_{\text{no pulse}} + \lambda P_{\text{exit in HI}} = 2.84 \times 10^{-8} \text{ failures/hour;}$$

for Pacemaker B:

$$\lambda P_{\text{no pulse}} = 1.9 \times 10^{-8} \text{ failures/hour}$$
$$\lambda P_{\text{exit in HI}} = 5.3 \times 10^{-19} \text{ failures/hour}$$
$$\lambda P_{\text{Total}} = 2.43 \times 10^{-8} \text{ failures/hour.}$$

Mission time was determined as two years, which are 17,520 hours. The failure probabilities needed for the decision tree of Figure 1 are presented in Tables 2 and 3. The expected utility (using the utility values of the previous section) for design A is 0.99994, and for design B 0.99989; hence design A is the preferred one. Again, this preference reflects a single decision maker, and no generalizations should be made. The two expected utility values seem very close, but the actual magnitude of a utility value is meaningless and has value only in comparison to other utility (or expected utility) values. The decision tree containing the probabilities and utility values is presented in Figure 3.

TABLE 2. PROBABILITIES FOR THE TWO PACEMAKERS

Pacemaker	P(OK)	P(no pulse)	P(exit in HI)
A	0.99950	4.552×10^{-4}	4.20×10^{-5}
B	0.99957	3.327×10^{-4}	9.28×10^{-5}

TABLE 3. CONDITIONAL PROBABILITIES OF FAILURE

Pacemaker	P(no pulse | failure)	P(exit in HI | failure)
A	0.909	0.091
B	0.782	0.218

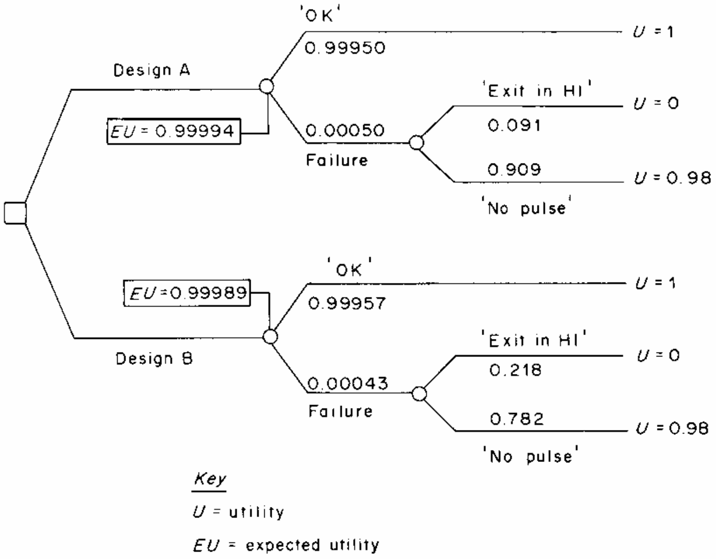

FIG. 3. *Decision tree and calculations for example.*

SENSITIVITY ANALYSES

As with any decision analysis, it is important to examine the stability of the solution by analyzing its sensitivity to changes in various parameters. From Figure 3 we see that the parameters of concern are the total failure rates for the two designs, the conditional failure mode probabilities, and the intermediate utility value for the 'no pulse' failure. The latter quantity is independent of the two example designs and is a universal figure for the *specific* cardiologist.

(1) *Sensitivity analysis of the cardiologist's preferences*

Specifically, the one quantity assessed by the cardiologist was the utility value of the 'no pulse' failure, U(no pulse). Let us calculate the utility value U_0 for which a shift in the decision from design A to design B would occur, leaving other elements of the decision problem unchanged.

$$EU(\mathrm{A}) = U_0(0.909)(0.0005) + (0.9995)(1)$$
$$EU(\mathrm{B}) = U_0(0.782)(0.00043) + (0.99957)(1)$$

Equating the two terms, we obtain $U_0 = 0.592$, compared to U(no pulse) = 0.98 which we originally used. This represents a substantial difference. Let us observe the implication of this number on the answer to the choice problem described earlier. If we leave $p_B = 0.001$, we obtain via the relationship $U(\text{no pulse}) = (p_A - p_B)/p_A$ a value $p_A = 0.00245$. This implies a defective rate of 2.45 per thousand as opposed to the 50 per thousand originally obtained.

There was no way, in the cardiologist's mind, that his indifference value could be that low. From informed communication with other cardiologists we observed that other subjective preferences will also result in a higher proportion than 0.245% of pacemakers having the less severe defect that would offset the one in a thousand pacemakers with the more severe failure.

(2) *Sensitivity analysis of the conditional failure probabilities*

The conditional failure probabilities of Figure 3 were from various 'manual' engineering assessments, and not 'mechanically' by the M.T.B.F. (Mean Time Between Failures) model of *MILHDBK 217C*. Therefore, they are the first probabilities to be questioned. In order to achieve a shift from design A to design B, the 'no pulse' probability of design B should increase to 0.878 (from 0.782), assuming all else remains constant, or the respective probability for design A would have to be reduced from 0.909 to 0.796. These shifts represent changes of 12–14% in magnitude, indicating a rather stable solution.

(3) *Sensitivity analysis of the M.T.B.F. model calculation*

We examine the implications of changes in the total failure rate on the optimal decision. First, let us assume that the failure rate on both designs is consistently higher (or lower) than originally used in Figure 3. This is a common engineering phenomenon that could arise, for example, from higher humidity and more fluids in the body environment surrounding the pacemaker. If the failure rate is C, where C is some constant (the same for both designs because we are assuming a consistent error in the M.T.B.F. model), we can determine the value of C that would cause a shift from design A to B. Calculations reveal that such a shift will not occur, regardless of the value of C.

If we examine for possible M.T.B.F. errors in one design only, we obtain that the total failure rate of design A must double to 0.001 for design B to be preferred. This magnitude of error is highly unlikely. If we vary the total failure rate for design B, it must be reduced to 0.0002 from 0.00043. This again is unlikely to be the case.

DISCUSSION

The paper considers only failures in the electronic circuit of cardiac pacemakers. Pacemakers can also fail because of problems in the electrode, battery exhaustion, ineffective sensing and infection. Therefore, the model of this paper is not a decision aid for the cardiologist in choosing one pacemaker over another, because that choice problem must consider all failures. Our model can be very valuable in the design and planning stage of the electronic circuit where cardiologists should interact with manufacturers to provide a desired level of electronic reliability. Given alternative designs, the approach of this paper can serve as a valuable decision aid for choosing a preferred design, deciding whether to introduce redundancy, choosing components, deciding on addition or deletion of components, and choice of technology.

The standard procedure of failure mode error analysis only checks for implication on the total M.T.B.F. of the circuit. Our approach puts the proper weights not only on the probability of failures but also on their criticality.

The model developed in this paper can also provide for setting minimal reliability standards for the electronic circuit. Based on cardiologists' preferences, manufacturers can plan for a certain level of reliability as reflected by total failure rate as well as by the distribution of the various failure modes. For example, the utility analysis can indicate the maximum proportion of 'exit in HI' failure relative to 'slow pulse' failures that could be acceptable.

Such an analysis can greatly enhance the process of designing the electronic circuit of the pacemaker. If we consider, for example, the formal analysis applied to the choice between designs A and B of Figure 2, the analysis could perhaps identify the 'weak' spots in each design and result in a third design, superior to both A and B. Such a use of the decision analytic framework is perhaps far more crucial than simply choosing one design or the other.

REFERENCES

[1] B. Ronen, J. S. Pliskin, S. Feldman and H. N. Neufeld (1979) Optimal choice of implanted cardiac pacemakers. *Proceedings of the VIth World Symposium on Cardiac Pacing*, Chap. 36–1.

[2] Faulty parts afflict pacemakers. *Electronics* (April 1975).

[3] Justice gets tough with pacemaker firm as companies seek high-reliability parts. *Electronics* (September 1975).

[4] H. Raiffa (1968) *Decision Analysis*. Addison–Wesley, Reading, Massachusetts.

[5] B. Ronen and J. S. Pliskin (1981) Decision analysis in microelectronic reliability: optimal design and packaging of a diode array. *Opns Res.* **29,** 229–242.

[6] *Military Standardization Handbook 217C, Reliability Prediction of Electronic Equipment*. Department of Defense, U.S.A. (September 1980).

[7] *SAM-D Reliability Prediction Notebook*. Assurance Engineering Department, Raytheon Company, Missile Systems Division, Bedford, Massachusetts (June 1973) (BR. 7675).

[8] H. Siddsons and E. Sowton (1967) *Cardiac Pacemakers*. Charles C. Thomas, Springfield, Illinois.