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# NBS SPECIAL PUBLICATION 400-42

U.S. DEPARTMENT OF COMMERCE / National Bureau of Standards

*Semiconductor Measurement Technology:*

## Reliability Technology for Cardiac Pacemakers II

A Workshop Report



00-42

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<sup>2</sup> Located at Boulder, Colorado 80302.

*Semiconductor Measurement Technology:*

**Reliability Technology for Cardiac Pacemakers II—  
A Workshop Report**

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Proceedings of a Workshop  
Held at the National Bureau of Standards  
Gaithersburg, MD, July 19-20, 1976

Harry A. Schafft, Editor

Electronic Technology Division  
Institute for Applied Technology  
National Bureau of Standards  
Washington, D.C. 20234



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Reliability Technology for Cardiac Pacemakers II

— A Workshop Report

Harry A. Schafft, Editor

Table of Contents

	Page
Introduction . . . . .	1
Highlights . . . . .	2
Summaries of Workshop Papers . . . . .	5
3.1 Process Validation Wafers for Use in Procuring Reliable Custom Integrated Circuit Chips <i>M. G. Buehler, National Bureau of Standards</i> . . . . .	5
3.2 High Reliability Microcircuit Procurement Controls <i>W. J. Kitchen, Jr. and T. H. Brown, National Security Agency</i> . . . . .	9
3.3 Mechanisms of Dendritic Growth <i>R. P. Frankenthal, Bell Laboratories</i> . . . . .	12
3.4 Use of Epoxies in Hybrid Microcircuits <i>R. F. Redemske, Teledyne Microelectronics</i> . . . . .	14
3.5 Microcalorimetric Study of Cardiac Pacemakers and Batteries <i>E. J. Prosen and J. C. Colbert, National Bureau of Standards</i> . . . . .	16
3.6 Statistical Methods for Estimating the Longevity of Pacemaker Batteries <i>D. J. Gerrard, Medtronic, Inc.</i> . . . . .	18
3.7 Applications and Pitfalls of Reliability Prediction <i>J. H. Maness and S. Kus, IIT Research Institute</i> . . . . .	19
3.8 A Reliability Comparison of Semiconductor and Microcircuit Technologies <i>H. A. Lauffenburger, Reliability Analysis Center</i> . . . . .	20
3.9 Moisture Measurement, Leak Rate, and Reliability <i>R. E. Sulouff, Martin Marietta Aerospace</i> . . . . .	22
3.10 The Fundamentals of Leak Testing for Cardiac Pacemakers <i>S. Ruthberg, National Bureau of Standards</i> . . . . .	25
3.11 Pacemaker Leads — A Physician's View <i>V. Parsonnet, M.D., Newark Beth Israel Hospital</i> . . . . .	30
3.12 The Performance of Implantable Pacing Leads — A Status Report <i>P. P. Tarjan, Cordis Corporation</i> . . . . .	33
Appendix: Workshop Program . . . . .	38



## PREFACE

The workshop on reliability technology for cardiac pacemakers was conducted as part of the Semiconductor Technology Program in the Electronic Technology Division of the National Bureau of Standards (NBS).

The Semiconductor Technology Program serves to focus NBS efforts to enhance the performance, interchangeability, and reliability of discrete semiconductor devices and integrated circuits through improvements in measurement technology for use in specifying materials in national and international commerce and for use by industry in controlling device fabrication processes. Its major thrusts are the development of carefully evaluated and well documented test procedures and associated technology and the dissemination of such information to the electronics community. Application of the output by industry will contribute to higher yields, lower cost, and higher reliability of semiconductor devices. The output provides a common basis for the purchase specifications of government agencies which will lead to greater economy in government procurement. In addition, improved measurement technology will provide a basis for controlled improvements in fabrication processes and in essential device characteristics.

The Program receives direct financial support principally from two major sponsors: The Defense Advanced Research Projects Agency (ARPA) and the National Bureau of Standards. The ARPA-supported portion of the Program, Advancement of Reliability, Processing, and Automation for Integrated Circuits with the National Bureau of Standards (ARPA/IC/NBS), addresses critical Defense Department problems in the yield, reliability, and availability of integrated circuits. Measurement oriented activity appropriate to the mission of NBS is a critical element in the achievement of the objectives of ARPA and other supporting government agencies.

Essential assistance to the Program is also received from the semiconductor industry through cooperative experiments and technical exchanges. NBS interacts with industrial users and suppliers of semiconductor devices through participation in standardizing organizations; through direct consultations with device and material suppliers, government agencies, and other users; and through symposia and workshops. In addition, progress reports are regularly prepared for issuance in the NBS Special Publication 400 sub-series. More detailed reports such as state-of-the-art reviews, literature compilations, and summaries of technical efforts conducted within the Program are issued as these activities are completed. Reports of this type which are published by NBS also appear in the Special Publication 400 sub-series. Announcements of availability of all publications in this sub-series are sent by the Government Printing Office to those who have requested this service. A request form for this purpose may be found at the end of this report.



Reliability Technology for Cardiac Pacemakers II

— A Workshop Report

by

Harry A. Schafft, Editor

Summaries are presented of 12 invited talks on the following topics: the procurement and assurance of high reliability electronic parts, leak rate and moisture measurements, pacemaker batteries, and pacemaker leads. The workshop, second in a series, was held in response to strong interest expressed by the pacemaker community to address technical questions relevant to the enhancement and assurance of cardiac pacemaker reliability. Discussed at the workshop were a process validation wafer concept for assuring process uniformity in device chips; screen tests for assuring reliable electronic parts; reliability prediction; reliability comparison of semiconductor technologies; mechanisms of short-circuiting dendritic growths; details of helium and radioisotope leak test methods; a study to correlate package leak rates, as measured with test gasses, and actual moisture infusion; battery life prediction; microcalorimetric measurements to nondestructively evaluate batteries for pacemakers; and an engineer's and a physician's view of the present status of pacemaker leads.

*Key Words:* Batteries; cardiac pacemakers; hermeticity; hybrid devices; leak testing; measurement technology; microcalorimetry; pacemaker leads; process control; reliability; semiconductor devices; screen tests.

## 1. INTRODUCTION

This workshop addressed the problems of procurement and assurance of high reliability electronic parts, leak testing of electronic components and pacemakers, and batteries and leads for pacemakers. It was held on July 19-20, 1976, at the National Bureau of Standards in Gaithersburg, Maryland, in response to strong interest expressed by the pacemaker community during an earlier workshop<sup>1</sup> and in a subsequent questionnaire.

The design of the workshop program was developed using inputs received from this questionnaire sent to attendees of the first workshop, and from subsequent follow-up phone calls to respondees selected to represent all attending pacemaker manufacturers. The topics of greatest interest, as indicated in the questionnaire, were screen and accelerated tests for procuring and assuring high reliability electronic parts, both active and passive. Of these tests, ones for hermeticity were of particular interest. Strong interests were also expressed in tests that can be used in the procurement and assurance of high reliability leads and power sources. Of somewhat lesser interest were electromagnetic interference and tests to assure the quality of metallic and nonmetallic materials, connections and interconnections, circuit boards, and chemicals.

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<sup>1</sup> Schafft, H. A., Ed., *Semiconductor Measurement Technology*: NBS/FDA Workshop, Reliability Technology for Cardiac Pacemakers, NBS Special Publication 400-28 (June 1976).

Telephone calls for more detailed input served to underscore the broad and active interest in discussions of and recommendations for accelerated and screen tests to assure reliable electronic parts. Strong interest in burn-in tests was expressed repeatedly. Other often raised problems were associated with short-circuiting dendritic and other growths at feed-throughs, battery terminals, circuit boards, and device terminals. The subject of preventing such growths is a complex one which, for example, touches on problems of assuring surface cleanliness and adhesion of epoxies.

At the workshop, twelve talks were presented in sets of four. After each set, the audience retired into four separate groups to discuss topics of interest with each speaker, in turn, as the speakers moved from group to group. An evening discussion session on power sources used in pacemakers was held at the end of the first day.

The workshop was attended by representatives from twelve domestic pacemaker manufacturers, one foreign pacemaker manufacturer, and three distributors of foreign-made pacemakers. Also among the 92 attendees were representatives of several battery vendors, the Food and Drug Administration, and other industrial and governmental organizations concerned with reliability.

Highlights of the presentations at the workshop are given in the next section of this report followed by a summary of each presentation, in the order that it was given; the workshop program is included as an appendix. Some of the results of the discussion periods are included in the highlights and the summaries. The summaries were prepared primarily from written materials provided by the speakers. Each speaker has read and approved the summary of his presentation.

## 2. HIGHLIGHTS

The need to balance efforts for screening-in reliability with efforts for building-in reliability was addressed by M. G. Buehler of NBS. He described the utility of the process validation wafer concept in the procurement of reliable, custom integrated circuit chips at an economical cost. This concept is adaptable to pacemaker manufacturers and other users of semiconductor devices who have need of relatively small numbers of very high reliability electronic parts. Process validation wafers incorporate specially designed test structures which can pinpoint process faults. These wafers are fabricated along with product wafers on a periodic basis to help insure that device chips have been processed uniformly.

Improved uniformity and repeatability of processing along with the use of effective screen tests can lead to greater system predictability. There is no consensus, however, on what are effective screens for any given device technology. The topic of burn-in and other accelerated and screen tests to assure reliable electronic parts is one in which the pacemaker community has a keen interest. No one speaker was able to address this broad and complex subject in its entirety, although portions of this topic were given attention by several speakers.

W. J. Kitchen and T. H. Brown of the National Security Agency discussed their procurement program which included the use of special test structures and device design features to build in reliability, as well as screen tests used in the procurement and assurance of high reliability microcircuits for their electronic systems. One test in particular which they have found to be very valuable is the nondestructive pull test for wire bonds. They have seen no field failure due to wire bonds since this screen test was adopted.

The use of epoxies in hybrid microcircuits has created much concern because of problems with the outgassing of these materials. R. E. Redemske of Teledyne Microelectronics described the steps in materials selection and process control that will allow the use of epoxies in hybrid devices without fear of reliability degradation.

Preliminary field failure-rate data for different semiconductor device technologies were reviewed by H. A. Lauffenburger of the Reliability Analysis Center. These data are being collected to check reliability models used in MIL-STD-217B to predict the reliability of electronic systems. Data analyzed thus far indicate failure rates for monolithic integrated circuits (ICs) to be about two orders of magnitude less than those for hybrid devices of comparable complexity. Some attendees criticized these data for hybrids saying that hybrid failure rates were far better than reported, while others said that the data confirmed theirs. The data also showed that the spread in failure rates for ICs is as large as one order of magnitude, even for the same conditions of manufacture and application. Lauffenburger indicated that the spread in failure rates for hybrid devices may be expected to be significantly higher than those for ICs because more technologies are involved in hybrid devices, and the processes to produce them are less standardized than they are for ICs. Thus, depending on the process controls exercised, considerable variation in reliability could be expected for hybrid devices.

In addressing the application and pitfalls of reliability prediction of electronic systems such as cardiac pacemakers, J. H. Maness and S. Kus of the Illinois Institute of Technology Research Institute discussed manufacturing process analysis as a means for eliminating design failures and reducing built-in defects which interfere with an accurate prediction of system reliability.

The problem of leak testing of semiconductor devices and pacemakers was addressed by two speakers. S. Ruthberg of NBS reviewed the use of the helium and the radioisotope methods for fine-leak testing. He pointed out, in particular, the advantages in shorter testing time that the radioisotope method offers when measuring leak rates of packages with internal volumes greater than about 1 cm<sup>3</sup>, such as for pacemaker containers. R. Sulouff of Martin Marietta Aerospace described NBS-sponsored work to establish a much-needed correlation between the leak rate of a package, as measured with a test gas such as helium, and the ingress of moisture. Such a correlation is a primary concern because without it no meaningful maximum allowable leak rate can be established for the leak test methods in wide use today. A part of this study is the evaluation

and use of small dew-point and oxide moisture sensors placed inside the semiconductor device package fitted with minute leak channels to simulate packages with leak rates in the range of from about  $10^{-4}$  to  $10^{-8}$  atm·cm<sup>3</sup>/s.

Exploratory work on a new method for studying batteries was discussed by E. J. Prosen of NBS. He described the equipment and plans for using microcalorimetric measurements to determine nondestructively the internal self-discharge energy of batteries and the dissipation energy in completed pacemakers. It is expected that this method may eventually be useful to predict the operational life of batteries used in implantable cardiac pacemakers, to gain better understanding of battery failure mechanisms, and to detect anomalous thermal behavior in completed pacemakers prior to implantation. Addressing a theoretical approach to the prediction of battery life, D. J. Gerrard of Medtronic, Inc., described a statistical method for predicting the life of mercury-zinc batteries. The approach may be generalized or at least should be suggestive of other approaches for dealing with a wider class of batteries.

Many questions, directed primarily to battery manufacturers, were discussed by the participants at the evening session on batteries which served to explore areas of concern without establishing consensus. These questions included: What is the definition of a qualified power source? How are new power sources qualified? How are existing qualified power sources requalified when changes are made in design or manufacturing specifications? and How does the pacemaker manufacturer assure the quality of incoming lots of power sources?

In response to keen interest in growths that can lead to short circuits and premature battery depletion, R. P. Frankenthal of Bell Laboratories discussed the mechanisms of dendritic growths. The levels of moisture and contamination below which such growths will not occur are not well defined, and the methods to measure such levels are not felt to be satisfactory for use in a production environment.

With the growing use of pacemakers by a younger population with a longer life expectancy, greater demands are being placed on the pacemaker lead — the wire that delivers electrical impulses to and from the heart. The need for improved lead technology will increase as this trend continues and the lead is required to survive the flexure stresses of tens of millions of heart beats per year and the corrosive environment of the body for a decade or more. These points were made by V. Parsonnet, Director of Surgery at the Newark Beth Israel Hospital, and P. Tarjan, Manager of Biomedical Engineering at the Cordis Corporation, who both addressed the topic of the pacemaker leads — one from the physician's and the other from an engineer's point of view.

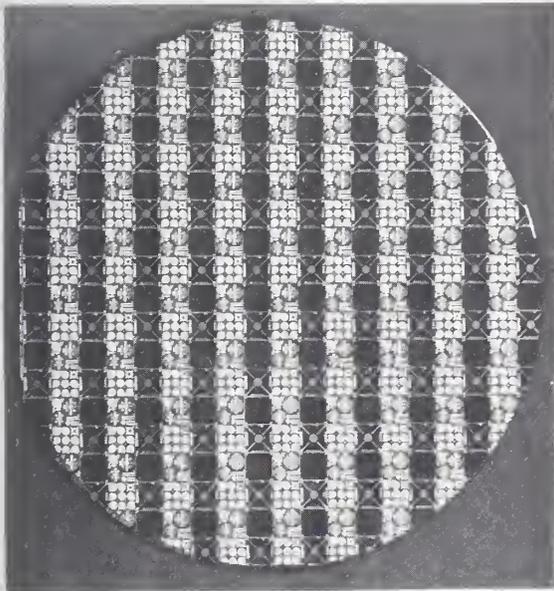
### 3. SUMMARIES OF WORKSHOP PAPERS

#### 3.1 Process Validation Wafers for Use in Procuring Reliable Custom Integrated Circuit Chips<sup>1</sup>

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Institute for Applied Technology  
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The procurement of reliable custom integrated circuits is an important national concern impacting both civilian and military interests. Current practices for procuring high reliability components have a number of shortcomings. One of them is overreliance on externally imposed process specifications which stifle vendor innovations that could take advantage of improved processes. Another is an overreliance on end-point screen tests which is most serious for complex circuits, because of the inability to test and stress the internal components which are unreachable from the external terminals. And finally, there is no assurance, by the current practice, that reliability is being built into the components and that the variations in the parameter values and the numbers of random faults are sufficiently small to make sample tests meaningful. Consequently, system performance and reliability suffer.

The key to built-in reliability at the wafer level is a high-yield process which implies: (1) conservative circuit requirements, (2) conservative layout rules, (3) a mature and stable process, and (4) uniform wafer parameters (i.e., processing, device, and random-fault parameters). The *process validation wafer* (PVW) is an economical vehicle for quantifying items 2, 3, and 4.



The PVW consists of test structures such as special resistors, capacitors, diodes, transistors, and circuits which are grouped into a test pattern which is repeated periodically over the wafer, as shown in figure 1. The power of such test patterns derives from the ability to provide generic information about individual wafer fabrication processes. Test structures such as those listed in table 1 can

Figure 1. Photomicrograph of a test pattern repeated over a 2-inch (50-mm) diameter silicon wafer.

<sup>1</sup>This work is supported in part by the Defense Advanced Research Projects Agency (Order No. 2397, Program Code 6D10).

be designed to be sensitive to specific parameters which in turn can reveal the control over the fabrication processes relative to, for example, intentional dopants, residual defects, topography, and random faults. An example of a test structure and the parameter distribution that can be obtained is shown in figure 2. The importance of this and other parameter distributions obtained must be determined for the particular circuit being fabricated.

Table 1. Test Structures for Process Control

Control Exercised Over	Parameter Measured	Test Structure Used
intentional dopants	epitaxial resistivity	resistor
	boron diffusion	resistor
residual defects	fast states	diode/MOS-capacitor
	oxide charge	MOSFET/MOS-capacitor
topography	mask alignment	resistor
	line width	resistor
	layer thickness	MOS capacitor
random faults	contact	resistor
	step coverage	resistor
	pin holes	transistor
	emitter-collector pipes	MOS capacitor
	crystalline defects	diode

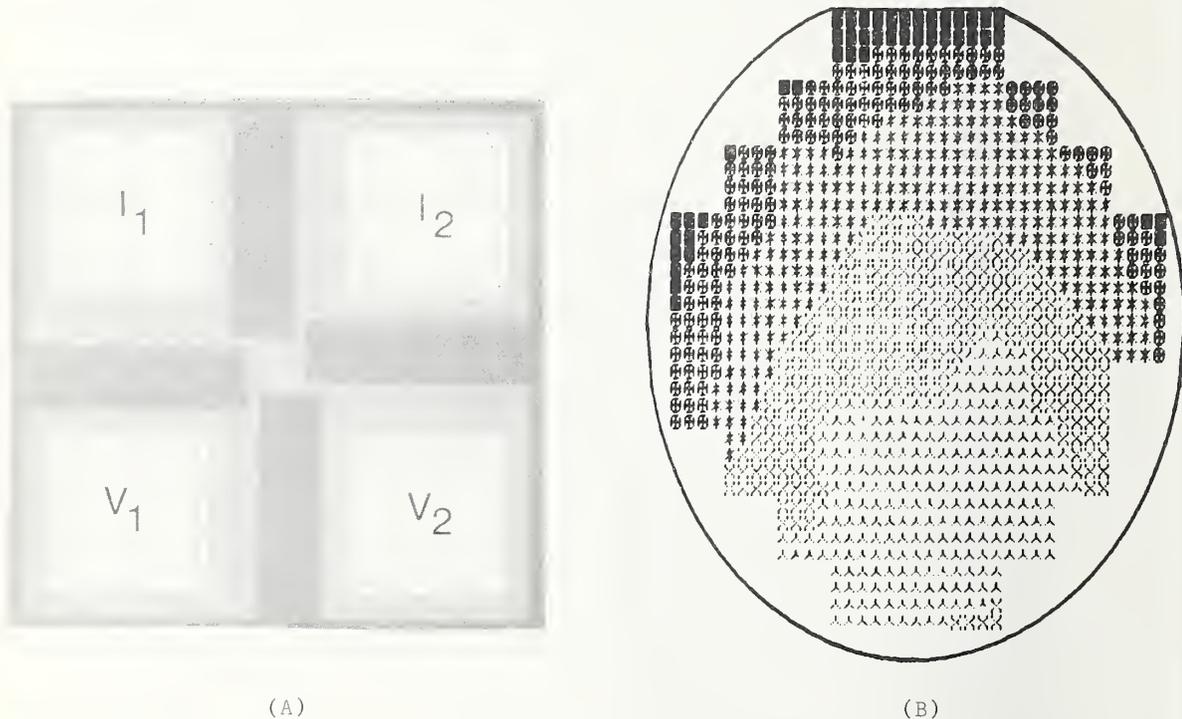


Figure 2. (A) van der Pauw sheet resistor where current is forced between  $I_1$  and  $I_2$ , and measured between  $V_1$  and  $V_2$ . Center-to-center separation between horizontal and vertical contact pads is 200  $\mu\text{m}$ . (B) Base sheet resistance variations across wafer as measured by test structure in A. Sheet resistance values are indicated by character density (from 173 to 191  $\Omega/\square$ , in 4.4- $\Omega/\square$  increments).

The concept of using PVWs involves their fabrication along with product wafers on a periodic basis. PVWs can play a vital role in the procurement of reliable, custom integrated circuit chips at an economical cost. They will help insure that reliability is built into the chips and this, along with effective screen tests, will lead to system predictability.

The PVW approach is economical because it does not require the alteration of the product wafer and it is not disruptive to the fabrication cycle. The information of the parameter distributions, which the PVWs supply, allows the establishment of a base line to evaluate process capability and stability. Furthermore, the approach obviates the need for extensive user-imposed manufacturing controls that inhibit process innovation by the manufacturer.

NBS has a project on test patterns whose goals are to develop and analyze recommended test structures, to demonstrate their usefulness, and to promote their application. A variety of publications on the work is available.<sup>2</sup> Mask sets for test patterns NBS-2<sup>3</sup> and NBS-3<sup>4</sup> are available on request.<sup>5</sup>

Test Pattern NBS-7, which consists of 40 test structures designed to evaluate TTL junction-isolated technology, is illustrated in figure 3. This pattern is

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<sup>2</sup>Buehler, M. G., *Semiconductor Measurement Technology: Microelectronic Test Patterns: An Overview*, NBS Spec. Publ. 400-6, August 1974.

Buehler, M. G., David, J. M., Mattis, R. L., Phillips, W. E., and Thurber, W. R., Planar Test Structures for Characterizing Impurities in Silicon, Extended Abstracts of the Electrochemical Society Meeting, Toronto, Canada, May 11-16, 1975, pp. 403-404.

Buehler, M. G., David, J. M., Mattis, R. L., Phillips, W. E., and Thurber, W. R., *Semiconductor Measurement Technology: Planar Test Structures for Characterizing Impurities in Silicon*, NBS Spec. Publ. 400-21, December 1975.

Buehler, M. G., and Thurber, W. R., A Planar Four-Probe Test Structure for Measuring Bulk Resistivity, *IEEE Trans. Electron Devices* ED-23, pp. 968-974, August 1976.

Galloway, K. F., and Buehler, M. G., The Application of Test Structures and Test Patterns to the Development of Radiation Hardened Integrated Circuits: A Review, NBSIR-76-1093, August 1976.

Buehler, M. G., and Sawyer, D. E., Microelectronic Test Patterns for Use in Procuring Reliable, Custom Integrated Circuit Chips, *1976 Government Microcircuit Applications Conference Digest of Papers*, Orlando, Florida, November 9-11, 1976, pp. 62-65.

<sup>3</sup>Buehler, M. G., *Semiconductor Measurement Technology: Microelectronic Test Patterns: An Overview*, NBS Spec. Publ. 400-6, August 1974.

<sup>4</sup>Buehler, M. G., *Semiconductor Measurement Technology: Microelectronic Test Pattern NBS-3 for Evaluating the Resistivity-Dopant Density Relationship of Silicon*, NBS Spec. Publ. 400-22, May 1976.

<sup>5</sup>Requests for releasing mask sets from a commercial mask-making company should be made directly to M. G. Buehler, National Bureau of Standards, Washington, DC 20234. The cost of each set is approximately \$200.

<sup>6</sup>Work is being carried out at RCA under NBS contract 5-35916.

arranged in a modular 2 by N probe-pad array (N is an arbitrary positive integer) which has been selected for NBS-developed test patterns. The reasons for such arrays are based on considerations of industry compatability and ease of testing, probing, and standardizing.

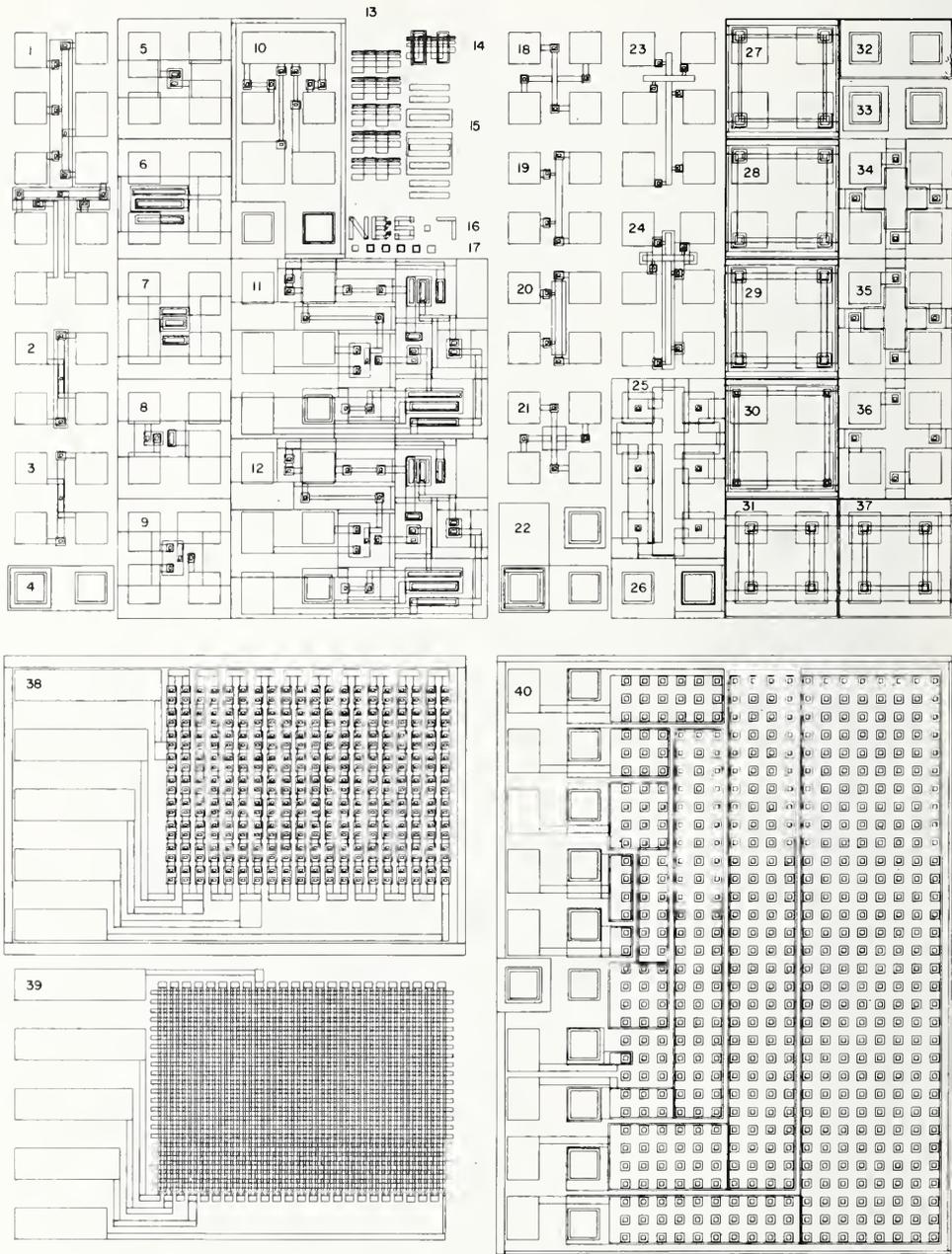


Figure 3. Test pattern NBS-7 for evaluating TTL junction-isolated process technology. The test pattern fits on a chip 3.4 mm by 2.6 mm. Forty test structures are included in the test pattern. Process parameter test structures such as sheet resistors and large area transistors are shown in structures 1 to 4 and 18 to 37. NAND gate structures are numbered 11 and 12 and their associated circuit elements are numbered 5 to 10. Miscellaneous elements such as alignment and resolution test structures are numbered 13 to 17. Random fault test structures include contact array (38), metal step coverage (39), and emitter-collector pipe (40) testers.

### 3.2 High Reliability Microcircuit Procurement Controls

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The concepts and controls effective in procuring high reliability electronics parts are predicated on the view, supported by experience, that component quality cannot be screened in; it must be built in.

In the NSA procurement program there are four areas of major emphasis: line certification, part qualification, screening matrices, and special screens. Line certification involves an evaluation of the process flow and the quality control procedures and documentation at the manufacturing facility prior to production; the option of reviewing the facility during production is included. All parts on high reliability programs must be qualified. Parts procured to MIL-STD-38510 are considered qualified — all other parts must be qualified according to a detailed plan which must be submitted by the vendor for evaluation. A screening matrix is developed for each part; the class A requirements of MIL-STD-38510 are used as a guide for microcircuits. Special screen tests and the sequence of tests are developed and used as appropriate.

Four efforts within this procurement program will be outlined here: test structures for process control, metallization systems and screens, assembly controls, and post-assembly controls or component "goodness" checks.

Test structures are used in various ways to assure process control. Test structures may be designed into the margins of each device; relatively limited process control information is obtained when they are used in this way. Test structures may consist of elements of the product circuit which are made accessible by a change in the metallization pattern. Such a group of test structures, or test pattern, is often used to provide information about process parameter spreads, technology characteristics, and design information for evaluating new technologies or new design rules. Such test patterns are also used to determine process compatibilities among vendors; at least two production sources are usually required for custom devices to insure adequate competition and supply.

Test patterns, consisting of specially designed test structures, distributed over an entire wafer may be processed along with product wafers to characterize process variability and stability over the wafer. Individual test patterns of this kind may also be substituted for a selected number of product devices on a wafer (usually 5) to obtain parameter and functional information for each product wafer. Information that is usually required from each product wafer for MOS devices are, for example, the gate and field threshold voltages, sheet resistivities, junction and oxide breakdown voltages, and the MOS gate conductivity.

Metallization in microcircuits is a potential source for many reliability problems. To avoid problems associated with intermetallic compound growths, all-aluminum interconnect systems are used whenever possible. To avoid gold-aluminum interfaces when packages with gold-plated terminals need to be used, a bonding island is utilized. The bonding island consists of a highly doped *p*-type silicon chip 180  $\mu\text{m}$  thick and 250 or 370  $\mu\text{m}$  on a side. The underside of the chip is gold plated and bonded to the terminal. The top side is sintered aluminum to which aluminum wire is ultrasonically bonded.

When aluminum-gold interfaces cannot be avoided, they are used only under the following special conditions: aluminum wire (25 to 250  $\mu\text{m}$  in diameter) is bonded to gold-plated package terminals where the gold is plated to a thickness between 2.5 to 5.0  $\mu\text{m}$  over nickel-plated Kovar<sup>1</sup> or nickel-plated tungsten; each device is then baked at 170°C for 30 h to allow the intermetallic compound growth to reach the nickel plating; all bonds are then subjected to a nondestructive pull test before the rest of the screen tests are performed.

An important screen for metallization is an examination with the scanning electron microscope (SEM) which is performed on each metallization lot. This examination has been extremely useful in detecting metallization problems early in production and in monitoring and documenting the quality of metallization. The test used is similar to Method 2018 of MIL-STD-883A except that the SEM facility must be certified and the operator must have at least one year of SEM operating experience and two years of semiconductor experience; an experienced semiconductor engineer may work with the operator in lieu of the latter requirement.

Among the assembly-control screen tests used are the destructive and nondestructive pull tests and the die shear test. For the destructive pull test, either one device out of fifty or two devices per shift, whichever is greater, are selected at random. The wire bonds on the devices selected are serialized before being pulled to destruction. The purpose of this test is to eliminate the chance of fabricating a large number of defective bonds and to gain confidence in the nondestructive test used.

The nondestructive pull test<sup>2</sup> is used as a 100 percent screen test; all wire bonds are subjected to the test. Pulling force levels used depend on the diameter

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<sup>1</sup>Certain commercial materials are identified in this paper in order to specify usage adequately. This identification does not imply recommendation or endorsement by the National Bureau of Standards, nor does it imply that the materials are necessarily the best available for the purpose.

<sup>2</sup>Adapted from Harman, G. G., A Metallurgical Basis for the Non-Destructive Bond-Pull Test, *12th Annual Proceedings, Reliability Physics 1974*, Las Vegas, Nevada, April 2-4, 1974, pp. 205-210. See also Tentative Recommended Practice for Non-destructive Pull Testing of Wire Bonds, ASTM Designation F 458-76T, *Annual Book of ASTM Standards*, Part 43 (November 1976).

of the wire tested. For 17- $\mu\text{m}$  (0.7-mil) and 25- $\mu\text{m}$  (1.0-mil) diameter wire, the pulling forces are 1 gf and 2 gf, respectively.<sup>3</sup> For wires with diameters of 50  $\mu\text{m}$  or greater, the pulling force is 6 gf. This screen test has been particularly valuable because no field failures due to wire bonds have been found since it was adopted.

The die shear test for die adherence is used because an x-ray test used earlier proved to be inadequate. Because of a lack of repeatability of quantitative shear force measurements, a qualitative criterion has been instituted. It is required that after the die has been sheared off, more than 75 percent of the bond area must still be covered with silicon residue. One percent of the devices in each lot is subjected to this test.

Among the post-assembly controls is a destructive physical analysis procedure. Here a sample of either 4 devices or 4 percent of the device lot (less than 500 devices), whichever is greater, is selected at random for analysis. For integrated circuits, the sample is submitted to hermeticity, internal visual, scanning electron microscope, destructive pull, and die shear tests. Results of the analysis are compared with the parts configuration analysis report supplied by the vendor. This report includes details of the fabrication and assembly processes; construction materials; a cross section of the component; and often photographs of key circuitry, in the case of microcircuits.

Accelerated life testing is also extremely useful to characterize the first lot of a manufacturer's product. High-temperature, reverse-bias testing is useful for aging diodes and transistors, while high-temperature operating tests are better suited for microcircuits.

The program for procuring high reliability parts has been evolutionary. As needs and technology changes have occurred controls have had to change or new ones be developed. Presently, for example, silver migration in diodes and cracked metalization in hybrids have been problems. To deal with them, qualification specifications are being generated for epoxies, and general controls for hybrid fabrication are being considered.

A system for procuring high reliability components must be tailored to applications and needs and be responsive to reliability goals and needed cost trade-offs. If the size of a particular program does not justify developing an extensive in-house test facility, then the option of working with an independent testing house should be considered. Estimates of labor costs in man-hours for the screen tests mentioned are given in table 1. The numbers represent an average obtained from many vendors and should be useful in estimating the cost of each test and, hence, the cost of implementing them.

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<sup>3</sup>One gram-force (gf) equals 9.8 millinewtons.

Table 1. Cost Estimates for Selected Quality Controls<sup>4</sup>

Control	Labor Time
Test Pattern Insertions	Depends on complexity and number of tests <sup>5</sup>
SEM Exam	18.8 hours/wafer
Die Shear	0.2 hours/die
Bonding Islands	0.04 hours/die
Pull Test (Nondestructive)	0.5 minutes/wire
Pull Test (Destructive)	0.7 minutes/wire
Parts Configuration Analysis	47.5 hours/part
Destructive Physical Analysis	6.9 hours/integrated circuit

<sup>4</sup>See also Schuster, R. P., and Fischer, R. D., Analysis of Electronic Component Screening Programs and Their Cost Effectiveness, *IEEE Trans. Manufacturing Technology* MFT-5, pp. 37-43, June 1976. [Editor]

<sup>5</sup>It is difficult to estimate the cost in man-hours or dollars. The dollar estimates for using a five-level silicon gate PMOS test pattern in five locations on the wafer is about \$1200 for the masks, \$200 for additional processing costs per run, and \$50 for testing costs per wafer. Although this is expensive, the importance of detecting problems at this stage cannot be overemphasized.

### 3.3 Mechanisms of Dendritic Growth

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The growth of metal dendrites in electronic devices eventually causes a short circuit and failure of the device. While there are many mechanisms by which metal dendrites or whiskers can grow, only those mechanisms that are associated with electrolytic corrosion will be considered.

These metal growths occur, given the proper environmental conditions, between two metallic conductors that are separated by an insulator and subjected to an applied voltage. For the growth to occur, the resistance of the insulator must be degraded sufficiently that anodic oxidation or corrosion of the anode will take place, and the corrosion product must be sufficiently ionized and mobile that it will migrate over the insulator surface to the cathode under the influence of the electric field and be electrodeposited there.

Because the electric field will be greater where the first ions have been deposited, the ions that follow will be attracted to and deposited there also. This is the beginning of the dendrite. As it develops, it will grow toward the anode and eventually short-circuit the two conductors.

The resistance of the insulator may be decreased simply by adsorption of moisture, the ionization of which will produce mobile carriers. Water on the surface

of the insulator may react with an ionizable and soluble group that is part of the insulator polymer. Moisture may also dissolve an ionizable impurity present on or near the surface, such as residues of body salts or solder fluxes, especially activated solder fluxes containing chlorides or other halides. The level of humidity that is dangerous cannot be predicted *a priori*. Different substrate materials have different adsorption isotherms for water. Different coatings have different rates of permeation; every organic coating is permeable to water vapor.

The environment that is necessary to cause corrosion and dendritic growths varies from metal to metal. For silver, only moisture is necessary. Under the influence of an applied voltage, silver oxidizes and the resulting silver cations are sufficiently mobile to migrate to the cathode. For gold, a complexing anion such as  $\text{Cl}^-$  or  $\text{CN}^-$ , is required to solubilize the corrosion product. Otherwise, only a solid film of gold hydroxide forms on the anode surface. This film is not appreciably soluble, and thus no mobile cations are available. The electrochemical conditions at the cathode must also be such that deposition can occur. Because almost all metals will corrode<sup>1</sup> in a chloride environment, it is essential to avoid chloride ions. For example, activated solder fluxes should never be used. While changing metallizations may help, it is not the real answer to a dendrite problem; avoiding contamination and using good manufacturing practices are.

Steady-state electrochemical studies may be insufficient to predict whether dendritic growth will occur in real systems. Studies should also be made under transient conditions because the electrochemical behavior under these conditions will, most likely, be very different from that for static conditions. For example, passivating films that are present under steady-state conditions may not have sufficient time to form under transient conditions. Also, the migration of the ions under the influence of the electrical field will be affected by transient phenomena. An example of the importance of transient analysis is the one for pulses in pacemakers in which the net flow of charge is zero. Zero net charge flow does not mean that corrosion will be zero because the times of the anodic and cathodic pulses are different. During a long pulse at a low current level, transport processes away from or towards each electrode can proceed further than during a short pulse. Thus, any ions formed during the short high current may have sufficient time to migrate away during the subsequent long low current pulse. In that case they will not be redeposited on the electrode from which they came and the result is that the net corrosion rate is different from zero.

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<sup>1</sup>Not all corrosion necessarily results in dendritic growth. Other mechanisms of corrosion may be operative. Any failure analysis should determine which corrosion mechanism is responsible. For a summary of corrosion mechanisms frequently encountered in electronic applications, see R. P. Frankenthal in *Properties of Electrodeposits: Their Measurement and Significance*, R. Sard, H. Leidheiser, and F. Ogburn, Eds., The Electrochemical Society, Inc., Princeton, N.J., 1975, p. 142.

### 3.4 Use of Epoxies in Hybrid Microcircuits

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The use of organic materials such as epoxies in hybrid packages has been a controversial subject, primarily because of potential problems related to their outgassing characteristics. Experience from four years of extensive use of epoxies in volume production has demonstrated that with the proper selection of materials and with adequate process control, the use of epoxies in hybrid microcircuits should not be considered a reliability hazard.

The use of epoxies for attachment purposes is attractive because epoxies can deform plastically to avoid dangerous stress levels due to thermal expansion mismatches of connected members, and because cure temperatures are typically lower than the melting points of metal systems used in hybrid fabrication.

Detailed investigations of epoxies were initiated because of the desire to avoid the high stress levels encountered in metal attachments resulting from differences in the thermal expansion coefficients of aluminum oxide substrates and both ceramic capacitors and large silicon chips. Even lead-tin eutectic alloys, when used to mount ceramic capacitors, can cause cracks in the ceramic on cooling to room temperature.<sup>1</sup>

These investigations resulted in selection criteria for epoxy materials for use in hybrids: (1) formulations with primary or secondary amine constituents should be avoided; single component epoxies are desirable; (2) epoxies used should not show significant outgassing at temperatures below 200°C, as determined by thermogravimetric analysis; and (3) no chemical reactions in the epoxy should occur below 200°C, as determined by a differential thermographic analysis.

The following incoming inspection procedures and tests for epoxies also evolved from these investigations. Acceptance of new shipment lots of epoxies includes taking an infrared spectrographic reading and comparing it with such readings from the originally qualified material. Other analytical measurements such as thermogravimetric analysis, viscosity, and metals content are also conducted.<sup>2</sup> In addition, a sample of the epoxy is used to mount components by normal production procedures and the parts are subjected to the normal screen tests and to a shear test.

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<sup>1</sup>Seeba, M. D., and Sears, R. A., Ceramic Chip Capacitor Attachment, 1976 Proceedings, 26th Electronics Components Conference, San Francisco, CA, p. 237.

<sup>2</sup>Various types of analysis methods for epoxies are described by Caruso, S. V., Licari, J. J., and Perkins, K. L., Design Guidelines for the Use of Adhesives and Organic Coatings in Hybrid Microcircuits, NASA Technical Memorandum X64908, December 1974.

Proper process control is also necessary to achieve reliable attachment with epoxies. Control of the amount of epoxy applied to the substrate is important. Equipment is available to dispense controlled quantities of epoxy at operator command. A silk screen process, an option for large production quantities, allows for the application of precise quantities of epoxy on precisely defined areas. This process cannot, however, be used with materials containing solvent systems. Ceramic capacitors are attached at the ends with metal-filled conductive epoxy to provide for both mechanical and electrical connection. Nonconductive epoxy is applied between the end pads to provide greater mechanical connection strength. It is also used to prevent the conductive epoxy from spreading beneath the capacitor and causing a short circuit.

Integrated circuits are attached with conductive epoxy although electrical connection is usually not required. This is done to reduce the number of different epoxies that need to be qualified and evaluated for use inside the microcircuit package. A secondary advantage is that this epoxy provides a small improvement in thermal conduction. Transistors and diodes do require conductive epoxy because current must pass through the attach system. These devices require a gold backing to achieve a stable ohmic contact to avoid drift with time and temperature of the saturation voltage and forward voltage drop.

The current density through the epoxy attach system should not exceed  $200 \text{ A/m}^2$ . Current spreaders in the form of a Kovar tab may be used to reduce the current density. Similarly, a heat spreader in the form of a beryllium oxide tab may be used to reduce the junction temperature if the power dissipation density is too high.

Epoxies should be cured in an oven with uniform temperature distribution and rapid thermal response. It should provide forced ventilation to avoid build up of organic vapors, and the door should not be opened during a cure cycle. An additional precaution from an outgassing standpoint is to use a somewhat longer cure time and a slightly higher temperature than the minimum recommended by the epoxy vendor to insure that the cross-linking process is complete. For example, a cure at  $155$  to  $160^\circ\text{C}$  for one hour would be recommended for a vendor-specified cure at  $150^\circ\text{C}$  for one-half hour. There is evidence that cured epoxies absorb water vapor quickly from room air. To avoid moisture in the sealed package, it is recommended that the hybrid device be subjected to a high temperature vacuum bake-out immediately prior to cover seal and that it not be exposed to room air after the bake-out.

### 3.5 Microcalorimetric Study of Cardiac Pacemakers and Batteries

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This continuing study was undertaken to test the feasibility of using microcalorimetry to study batteries or power cells for cardiac pacemakers and of developing nondestructive test methods for cells and pacemakers to improve the prediction of their useful life.

The self-discharge characteristic of a battery is not completely understood and varies for different types of power cells, for different manufacturing methods, and sometimes for individual batteries produced under manufacturing conditions which are presumably the same. Microcalorimetry offers a way to nondestructively measure the open-circuit self-discharge of batteries and discover cells which have inordinately large self-discharge rates. With such information, limits can be set for the length of time the power cells can be stored before use and for the conditions (of temperature, for instance) under which the cells should be stored. Furthermore, the availability of such a measurement tool would be invaluable in efforts to reduce self-discharge by cell and process redesigns.

It is also not clear if this self-discharge is present or not when the power cell is under load as when operating in a pacemaker. This question needs to be addressed. Typical pacemakers may draw as little as 25  $\mu\text{W}$  of power. It is not unreasonable to expect a self-discharge power of 5  $\mu\text{W}$  for pacemaker batteries, which if present under load conditions, would be responsible for a significant reduction in the life of the battery.

The microcalorimeter<sup>1</sup> used for preliminary measurements employs a solid-state thermopile detector which has an output of 1  $\mu\text{V}$  per 4.90  $\mu\text{W}$  of power generated within the sample box. The detector output is amplified by an operational amplifier kept at constant temperature within the calorimeter jacket. This output voltage is then recorded by a millivolt potentiometer recorder or it is read by a digital voltmeter, recorded on a magnetic tape cassette, and digitally plotted. The sensitivity of the microcalorimeter is such that a few tenths of a microwatt of power can be detected. The silver sample box is too small to accommodate pacemaker power cells. Therefore, small disc-type camera and watch power cells were

<sup>1</sup>Prosen, E. J., Design and Construction of the NBS Clinical Microcalorimeter, NBS Report 73-179, April 1973.

Prosen, E. J., and Goldberg, R. N., Testing of the NBS Clinical Microcalorimeter, NBS Report 73-180, April 1973.

Prosen, E. J., Goldberg, R. N., Staples, B. R., Boyd, R. N., and Armstrong, G. T., Microcalorimetry Applied to Biochemical Processes, *Thermal Analysis: Comparative Studies on Materials*, H. Kambe and P. D. Garn, Eds., John Wiley and Sons, New York, 1974, pp. 253-289.

used to test the feasibility of the microcalorimeter method for this work. A microcalorimeter capable of measuring the larger power cells for cardiac pacemakers and for measuring the pacemakers themselves is being assembled.

The output from the microcalorimeter during the process of measuring the self-discharge of a mercury battery for use in a watch is displayed in figure 1. The initial portion of the output curve is the baseline of the calorimeter with the sample box empty. Because the power cell is initially not very close in temperature to the calorimeter block, a large offset is first observed as the cell is inserted and the block temperature is disturbed slightly. A more reliable effect is observed upon removal of the power cell when the only disturbing effect is a slight frictional effect of removing the cell.<sup>2</sup> A signal of  $0.4 \mu\text{V}$  (the vertical height shown) at the thermopile is recorded on removal of the cell, which corresponds to  $2.0 \mu\text{W}$ , and is the self-discharge rate of the power cell.

Preliminary measurement results of a small sample of alkaline-type power cells (for camera use) and mercury-type power cells (for camera or watch use) yielded 4 to 5  $\mu\text{W}$  and 1.5 to 2  $\mu\text{W}$  self-discharge power, respectively. A test of a power cell with a resistor across it in the calorimeter yielded a power value in fair agreement with that calculated as dissipated across the resistance load plus the self-discharge.

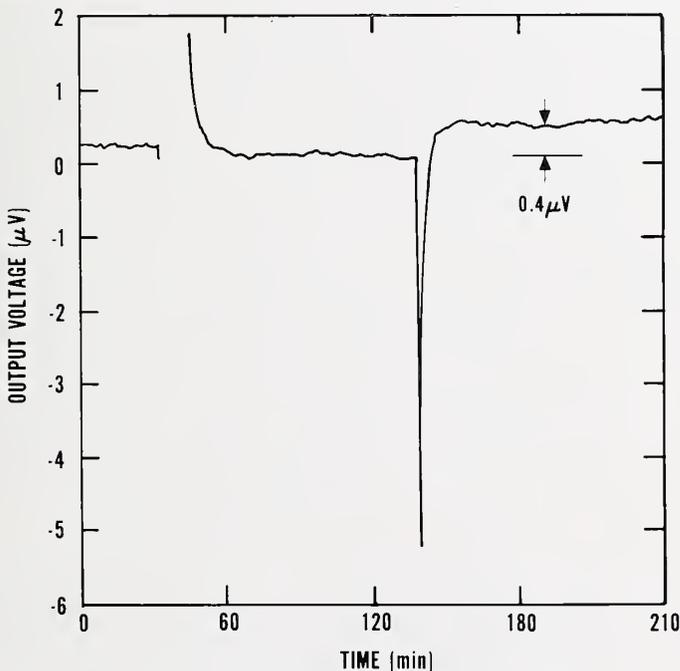


Figure 1. Microcalorimeter output voltage versus time as the mercury battery is inserted in the sample box at 33 min and removed at 138 min. An output of  $0.4 \mu\text{V}$  is indicated which corresponds to  $2.0 \mu\text{W}$  self-discharge power.

<sup>2</sup>To improve thermal contact of the power cell with the sample box, hydrocarbon oil was placed in the sample box so as to almost cover the power cell. Adhesive tape was placed over one terminal of the cell to prevent shorting to the box.

Tests of internal power,  $W_i$ , dissipated in the power cell in the calorimeter as a function of external power,  $W_x$ , dissipated in a resistor outside the calorimeter yielded results which are characteristic of the ideal cell reaction; that is,  $W_i$  is a linear function of  $W_x$  (within the precision of the measurements). This was true for both the alkaline and the mercury power cells tested within the precision of the present tests. A search for thermodynamic data on the cell reactions involved has not as yet been made for comparison with these experimental results. More thorough and accurate measurements of  $W_i$  versus  $W_x$  will need to be made in order to be able to state whether self-discharge or leakage is enhanced or absent when the power cell is in use (under load). Nondestructive tests of power output of complete pacemakers will also be made.

### 3.6 Statistical Methods for Estimating the Longevity of Pacemaker Batteries

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The life of a pacemaker battery and, hence, of the pacemaker itself, may be expressed in terms of two important probability functions: the survival probability,  $R(t)$ , and the monthly failure rate,  $p(t)$ . The data necessary to estimate these functions may be obtained from accelerated battery tests, the acceleration factors typically being temperature or current drain.

The statistical method considered is for the mercury-zinc electrochemical system with normal anode depletion as the failure mechanism. It is meant to serve as a demonstration of statistical modeling for estimating battery life. The approach may be generalized to a wider class of power sources or at least be suggestive of analogous methods for dealing with similar systems.

From empirical and electrochemical considerations, the depletion rate in a mercury-zinc system being drained by a current,  $I$ , may be represented by

$$\frac{dQ_t}{dt} = - (I + kQ_t), \quad (1)$$

where  $Q_t$  is the capacity remaining in the cell at time  $t$ , and  $k$  is the rate of chemical loss due to self-discharge mechanisms. Solving for  $t$  and expanding in a Taylor series the following approximation for the chemical loss,  $k$ , is obtained,

$$k \approx 2 \frac{T - t}{Tt} \quad (2)$$

where  $T = \lim_{k \rightarrow 0} t = \frac{Q_0}{I}$ , the common estimate of service life in an ideal battery;

$Q_0$  is the initial cell capacity.

Because  $k$  has been found to be essentially independent of  $I$  for  $I < 200 \mu A$ ,

eq (2) allows a transformation to be made from the observed lifetime,  $t_1$ , of a cell at an accelerated drain of  $I_1$ , to the equivalent lifetime,  $t_2$ , at pacemaker current drain  $I_2$ . This equivalence relation, using eq (2), is

$$t_2^{-1} = t_1^{-1} + (I_2 - I_1)/Q_0. \quad (3)$$

Thus, end-of-life distributions can be forecast, data from different current accelerated tests can be merged, and equivalent incompleting lifetimes from incompleting accelerated lifetimes can be projected.

To obtain an analytical representation for  $R(t)$  and  $p(t)$ , it is necessary to fit an appropriate probability distribution function to individual life table estimates, which can be obtained by the so-called actuarial method.<sup>1</sup> This requires that the finite range of battery lifetime be transformed to a scale ( $y$ ) from zero to infinity. One such transformation that has been found to be effective in conjunction with the Weibull distribution is  $y = Tt/(T - t)$ . The resulting forms for  $R(t)$  and  $p(t)$  are then

$$R(t) = \exp(-\alpha(Tt/(T - t))^\beta), \text{ and} \quad (4)$$

$$p(t) = 1 - R(t)/R(t - 1). \quad (5)$$

A convenient way to estimate the parameters  $\alpha$  and  $\beta$  is to evaluate them from the straight line relationship

$$\ln(-\ln R(t)) = \ln \alpha + \beta \ln(Tt/(T - t)).$$

Because  $y = Tt/(T - t)$  and  $k$  is independent of current drain (for  $I \leq 200 \mu\text{A}$ ),  $\alpha$  and  $\beta$  are also independent of current drain. Hence, eq (4) defines, for appropriately selected values of  $T$ , the battery end of life distribution for any current drain less than  $200 \mu\text{A}$ .

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<sup>1</sup>Berkson, J., and Gage, R. P., Calculation of Survival Rates of Cancer, Proceedings of Staff Meeting, Mayo Clinic 25, 1950, p. 270.

### 3.7 Applications and Pitfalls of Reliability Prediction

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The reliability of an implantable cardiac pacemaker is the probability that the pacemaker system as a whole will achieve its designated performance goal when operated under specified environmental conditions and implanted with reasonable care.

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<sup>1</sup>Now with American Hospital Supply Corporation, 17752 Skypark Boulevard, Irving, CA 92714. Tel. (714) 754-1800.

Reliability prediction using MIL-HDBK-217B or an equivalent procedure does not reflect the reliability potential of a pacemaker system during its useful life period. This estimate depicts the inherent reliability of the design as indicated by its engineering documentation, basic stress-strength design factors, and application factors. The estimate does not represent, however, the operational reliability unless design failures have been eliminated and manufacturing and quality defects have been minimized. Lack of an effort in these areas can result in a system reliability as low as ten percent of its inherent reliability.

Manufacturing process analysis<sup>2</sup> offers a way of minimizing reliability degradation due to production imperfections. Process analysis is a structured approach for identifying all steps in the manufacturing process which can affect reliability and for systematically ranking the effectiveness of screen tests to reduce the defect rates. Inherent as well as process induced defects are included in the analysis, as well as subsystem and even component analyses.

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<sup>2</sup>Anderson, R. T., Reliability Design Handbook, Rome Air Development Center, March 1976.

### 3.8 A Reliability Comparison of Semiconductor and Microcircuit Technologies

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Based on the data available at this time, there are notable differences in the inherent reliability of discrete devices, monolithic integrated circuits (ICs), and hybrid circuits. The hybrid circuit data used are preliminary, however. They are taken from a special data collection program now in progress for the purpose of reviewing the reliability prediction model for hybrid circuits in MIL-HDBK-217B.

The data indicate failure rates for hybrid circuits to be two orders of magnitude higher than those for discrete devices and ICs. Comparative field-use failure rates are given in figure 1 for selected groups of devices in each of the three device technologies. Failure rates of hybrid circuits are heavily influenced by complexity as measured in terms of the number of package leads and number of active chips. This is demonstrated in data shown in table 1 for devices screen-tested to conditions approximated by class B of MIL-STD-883A and operated in an airborne environment.

Reasons for the high failure rates for hybrids may in part be due to the process methodology and process controls which are less well defined for hybrid technology than they are for the more mature discrete and IC technologies. An additional factor may be the lack of a uniformly applied high reliability series of screen tests for hybrid devices.

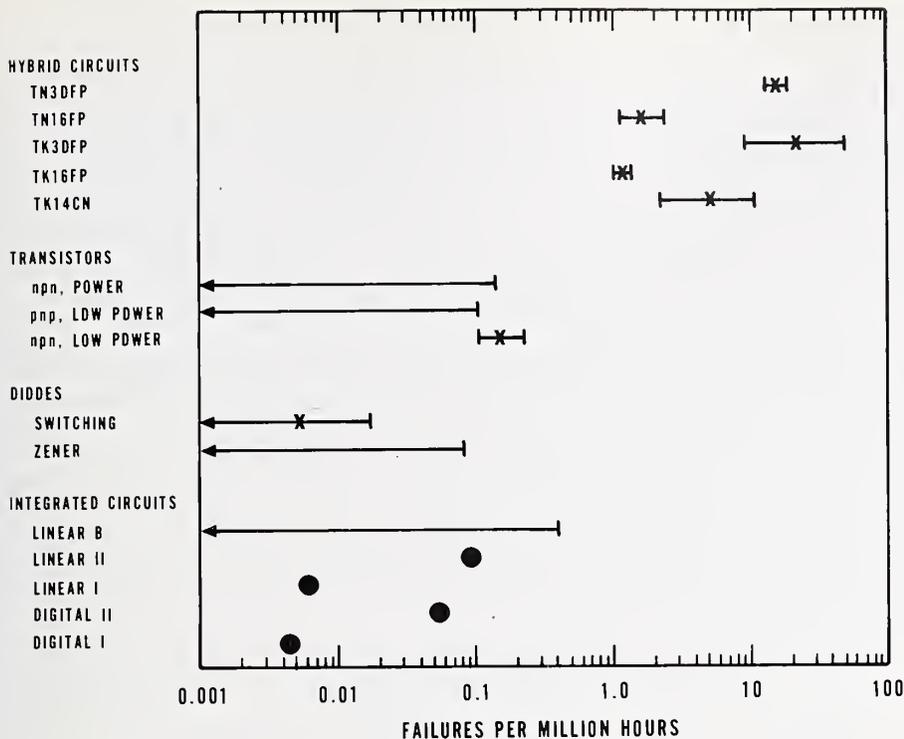


Figure 1. Comparative field-use failure rates for different device types. Best estimate failure rate points (x) for airborne environments are shown with 80 percent confidence intervals (10%, 90% points). A solid arrowhead is meant to indicate that the lower limit of the interval is below 0.001 failures per million hours. In cases where no point is shown, no failures were observed and only an upper confidence limit is indicated. Best estimate failure rate points (●) for class A screened devices in benign ground environments have confidence intervals too narrow to be shown.

Table 1. Effect of Circuit Complexity on Hybrid Microcircuit Failure Rates

Hybrid Technology	Complexity		Failures per 10 <sup>6</sup> hours
	Number of Package Pins	Number of Active Chips	
Thin Film	16	2 to 16	2.0
	30	5 to 16	15
	74	12 to 35	29
Thick Film	16	3 to 10	1.3
	30	6 to 10	25

While there are notable differences in the inherent reliability between the various technologies, the failure rate levels actually achieved can depend heavily on post production screen testing and operational stresses. This is demonstrated by the spread in failure rates for a given technology as shown by data in figure 1 for the last four entries (linear and digital ICs).

It is evident from figure 1 that the highest reliability levels can be achieved with ICs. While individual discrete device failure rates approach those of ICs, system failure rates will be substantially higher because of the quantity of devices used in the circuit. The circuit failure rate for discrete devices may be higher than for the equivalent hybrid circuit because of considerations related to the reliability of printed circuit bonds, passive components, solder connections, etc. used in the circuit with discrete devices.

It should be emphasized that the data presented here are for broad generic device classes and cannot be used for making accurate predictions for a given device class. The sources for the data quoted here and that compiled by the Reliability Analysis Center (RAC) are mostly military systems contractors and field maintenance depots. RAC is not involved with analyses of failed devices nor is it able to determine if the devices failed because of a damage-causing agent, although, with respect to the latter, there are provisions in the reporting system for recording such information.

### 3.9 Moisture Measurement, Leak Rate, and Reliability<sup>1</sup>

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Correlations between semiconductor device reliability, moisture infusion, and leak rates of device packages are of vital importance for meaningful specification of the hermetic nature, or hermeticity, of the package. Yet even now little quantitative information exists about such correlations, and the specifications for maximum allowable package leak rates which are now in use have been selected more for ease of measurement and correlation between test methods than for purposes of assuring device reliability.

Hermeticity is measured by several methods. All use some test fluid or gas whose measurement is related to the leak rate for dry air infusion.<sup>2</sup> The correlation with water vapor infusion is not considered in these tests. Yet this gas is the catalyst if not the agent for a significant percentage of device failures.

Correlation of test results to water vapor infusion is not considered because the infusion of water vapor is extremely difficult to predict due to the special chemical nature of the water molecule dipole and its interaction with surfaces. The

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<sup>1</sup>This work is supported by the Defense Advanced Research Projects Agency (Order No. 2397, Program Code 6D10) under NBS Contract No. 5-35880.

<sup>2</sup>For example, the use of mass spectrometry following a pressurization of helium measures the leak rate for helium. The use of krypton 85 in a pressurized chamber followed by a radioactive counting technique provides a leak rate for krypton gas. A commonly used gross leak test uses a fluoro-inert fluid.

build-up of water in monolayers until a meniscus is formed can result in either a plugging effect or an acceleration of water infusion because of evaporation and surface tension. Whether plugging or accelerated infusion occurs will depend on conditions that cannot be readily determined, such as the size of the leak channel in the package. Barometric pressure changes can also result in pumping effects.

The leakage of moisture into a package or the presence of moisture trapped inside the package will typically reduce the operating life of an electronic circuit. Questions that cannot yet be answered with confidence are: how much will the operating life be reduced by the presence of an arbitrary level of moisture, and what should be the maximum allowed moisture level within the package?

In mind of these uncertainties, a study was begun to establish relations between moisture infusion and leak size, and between internal moisture levels and failure rates. The results of the study are intended to provide a technical base to establish more meaningful maximum leak rate specifications. Because the rate of moisture infusion appears to be much slower than the infusion of the test gases, it may be possible to relax the maximum leak rate specifications that are now generally used — depending on the device lifetime desired.

The study consists of three tasks. The first involves an evaluation of two types of moisture sensors, oxide and dew point, which can be placed inside the package and monitored electrically through the package terminals. Packages with special NBS-constructed valves to introduce air with controlled amounts of moisture will house these sensors. One of the special packages with sensors in place is shown with the top removed in figure 1A. A package with access valves is shown in figure 1B. Two access valves are used so that the air-moisture mixture may be flushed through the package during calibration and during filling.

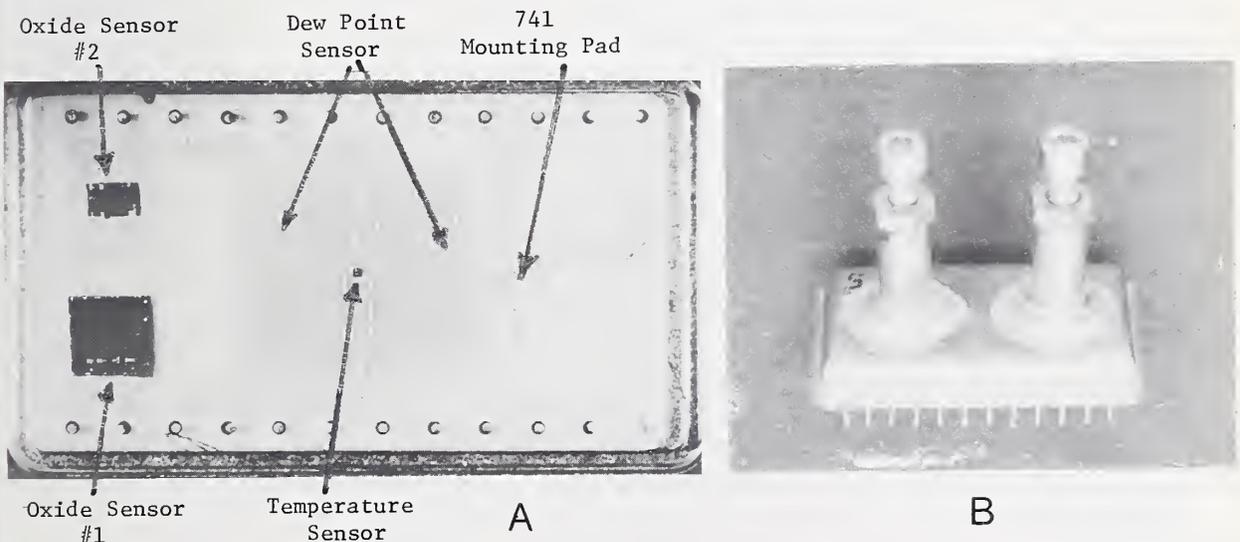


Figure 1. A. Test package with circuit configuration for moisture calibration and measurement tasks. B. Package with access valves.

The second task is to evaluate the feasibility of using the empty package itself, with one terminal wire bonded to the die-attach area, as the dew-point sensor for production line use, and to use such sensors to determine the moisture content of typical package types assembled on product lines.

The third task involves a long-term (5000 h) test of 220 packages fitted with special microchannels to simulate package leaks with leak rates<sup>3</sup> from  $10^{-5}$  to  $10^{-8}$  atm·cm<sup>3</sup>/s. The microchannels are formed by gold plating electropolished holes drilled by a laser beam as indicated in the sequence in figure 2. For stability, the microchannels are formed in the top of protrusions of test packages in the manner shown in figure 3. The packages contain moisture sensors and unpassivated type 741 operational amplifier dice and will be subjected to an environment of 85°C and 85 percent relative humidity during the test. Periodic readings will be made of the moisture sensors and the operational amplifier in each package to obtain information about the moisture infusion versus leak size, and moisture content versus failure rate during the term of the test.

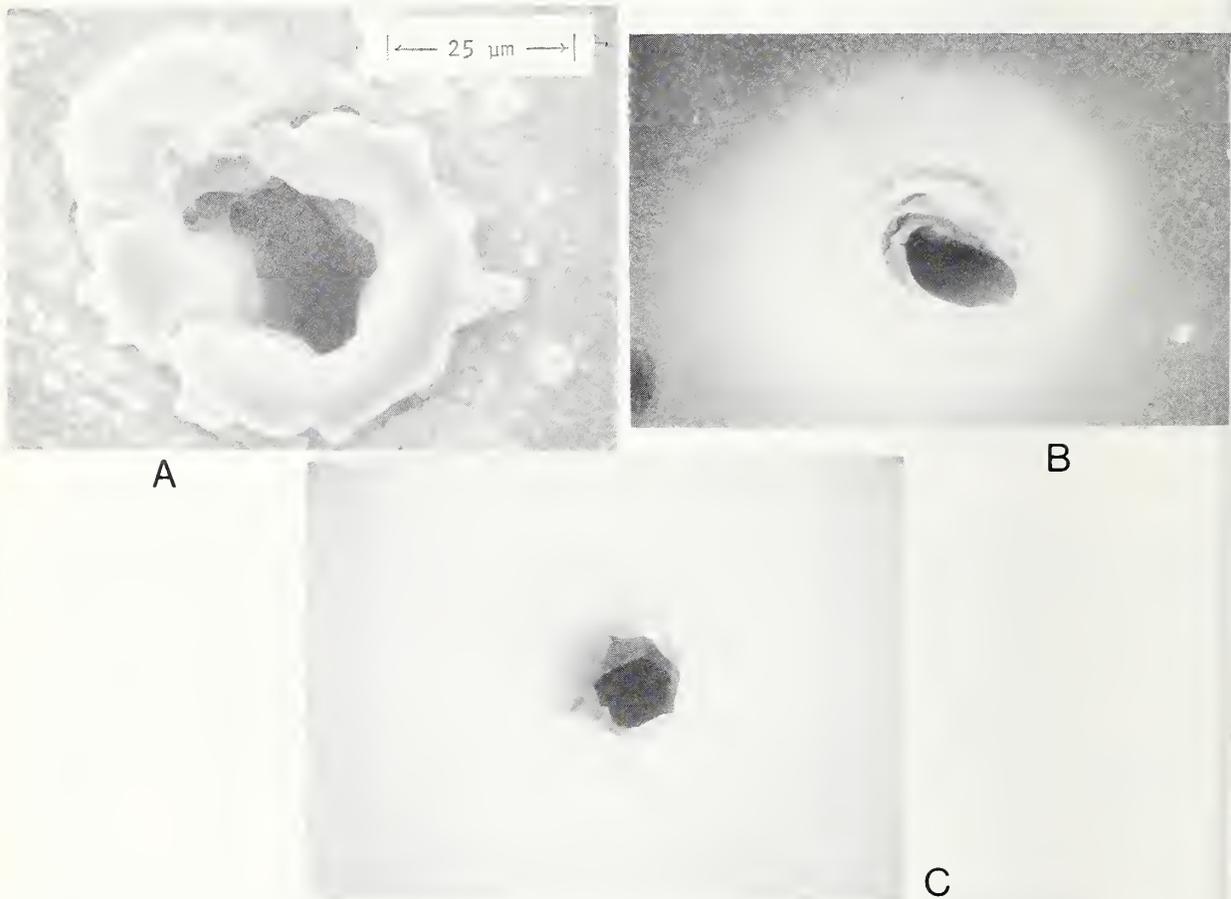


Figure 2. Fabrication sequence for microchannel production: A. laser-drilled hole, B. electropolished hole, C. gold-plated hole.

<sup>3</sup>Leak rate is commonly given in units of atm·cm<sup>3</sup>/s ( $10^{-1}$  Pa m<sup>3</sup>/s). [Editor]

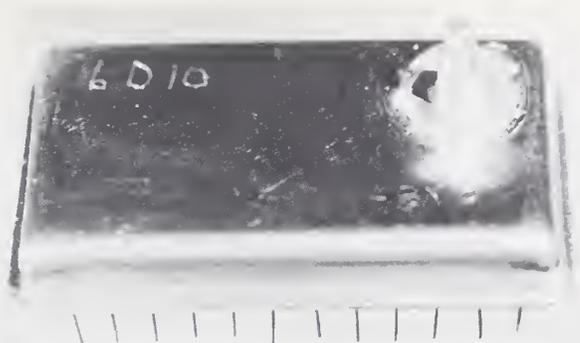


Figure 3. Package with microchannel (on top of protrusion).

### 3.10 The Fundamentals of Leak Testing for Cardiac Pacemakers<sup>1</sup>

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At least three leak test methods are presently required to cover the entire leak rate range of interest. For detecting leaks greater than about  $10^{-1}$  atm·cm<sup>3</sup>/s only a visual inspection method is effective. For smaller but still gross leak rates ( $\geq 10^{-5}$  atm·cm<sup>3</sup>/s), the weight gain method<sup>2</sup> is preferred among the methods available because it provides quantitative measures, it has the lowest escape rate, and it has a low overkill rate.<sup>3</sup> In the fine leak range ( $\leq 10^{-5}$  atm·cm<sup>3</sup>/s), the back pressurization helium leak detector<sup>4</sup> and the radioisotope<sup>5</sup> methods are widely used.

The back pressurization helium leak detector method involves pressurizing the package in helium, transferring the package to a helium mass spectrometer leak detector, and obtaining a machine reading of the helium gas escaping the package. The

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<sup>1</sup>This work is supported in part by the Defense Advanced Research Projects Agency (Order No. 2397, Program Code 6D10).

<sup>2</sup>Stinnett, D., Der Marderosian, A., and Nelson, P., Weight Test Method Detects Gross Leaks in Components, *Evaluation Engineering* 9, pp. 12-17, Sept./Oct. 1970. Also, Method 1014.1, Test Condition E — Military Standard 883A, Test Methods and Procedures for Microelectronics, November 15, 1974.

<sup>3</sup>Banks, S. B., McCullough, R. E., and Roberts, E. G., Investigation of Microcircuit Seal Testing, Report No. RADDC-TR-75-89 (April 1975).

<sup>4</sup>Howl, D. A., and Mann, C. A., The Back-Pressurizing Technique of Leak-Testing, *Vacuum* 15, pp. 347-352, March 1965. Also, Method 1014.1, Test Condition A — Military Standard 883A, Test Methods and Procedures for Microelectronics, November 15, 1974.

<sup>5</sup>Cassen, R., and Burnham, D., A Method of Leak Testing Hermetically Sealed Components Utilizing Radioactive Gas, *International Journal of Applied Radiation and Isotopes* 9, pp. 54-59, December 1960. Also, Method 1014.1, Test Condition B — Military Standard 883A, Test Methods and Procedures for Microelectronics, November 15, 1974.

correlation of the machine reading and the package leak rate depends on the gas flow mechanisms into and out of the part, the pressurization parameters, internal free volume, and the delay time between pressurization and measurement.

A major difficulty with the helium leak detector method (as well as with the radioisotope method) is in devising appropriate equations to relate machine readings to leak size. Traditionally, it has been assumed that molecular flow applies for the entire leak-rate range of the method ( $10^{-2}$  to  $10^{-8}$  atm·cm<sup>3</sup>/s), while it really only applies for the fine leak rate end of this range. The molecular flow equation used in the helium leak method to relate the detector reading, Q, to the helium leak rate,  $\ell$ , for the leak is

$$Q = P_E \ell \left\{ \frac{1}{P_O} [1 - \exp(-\frac{\ell}{P_O V} t_1)] \exp(-\frac{\ell}{P_O V} t_2) \right\} \quad (1)$$

where  $P_E$  = helium pressure during pressurization, atm,

$P_O$  = ambient atmospheric pressure, atm,

$V$  = internal free volume, cm<sup>3</sup>,

$t_1$  = pressurization time, s, and

$t_2$  = delay time between pressurization and detector measurement, s.

The term within the brackets describes the pressure rise within the package during pressurization. The second exponential term describes the reduction in helium pressure after pressurization. The braced expression represents the relative amount of helium within the package at any given time and is called the internal fractional helium pressure, F. Hence,

$$Q = P_E \ell F. \quad (2)$$

Solutions for eq (1) can be obtained from figure 1, where F is plotted against the relaxation rate,  $\ell/P_O V$ . The solutions extend from fine leaks, on the left, to gross leaks, on the right. Note that there will be conditions where a fine leak will give the same detector reading as a gross leak. In using figure 1 one should remember that  $\ell$  is the package leak rate for helium while reject specifications for leak rate (L) are for air. The ratio of helium to air molecular flow is about 2.7, therefore  $\ell = 2.7 L$ .

While the minimum and maximum leak rates for air,  $L_{\min}$  and  $L_{\max}$ , for a given set of test conditions can be obtained from figure 1, they are most conveniently determined from figures 2 and 3, respectively.<sup>6</sup> Some words of caution are offered in the use of these two figures; they apply only for certain leak rate ranges.

In determining the minimum leak rate from figure 2, the curves include no dependence on  $t_2$ . Hence the relaxation rate (leak rate) is small enough so that the second exponential term in eq (1) is essentially unity. Depending on  $t_2$ , this is the case for

<sup>6</sup>Figures 2 and 3 were adapted from figures 1 and 2 of Tentative Recommended Practices for Determining Hermeticity of Electron Devices with a Helium Mass Spectrometer Leak Detector, ASTM Designation F 134-72T, *Annual Book of ASTM Standards*, Part 43, 1976.

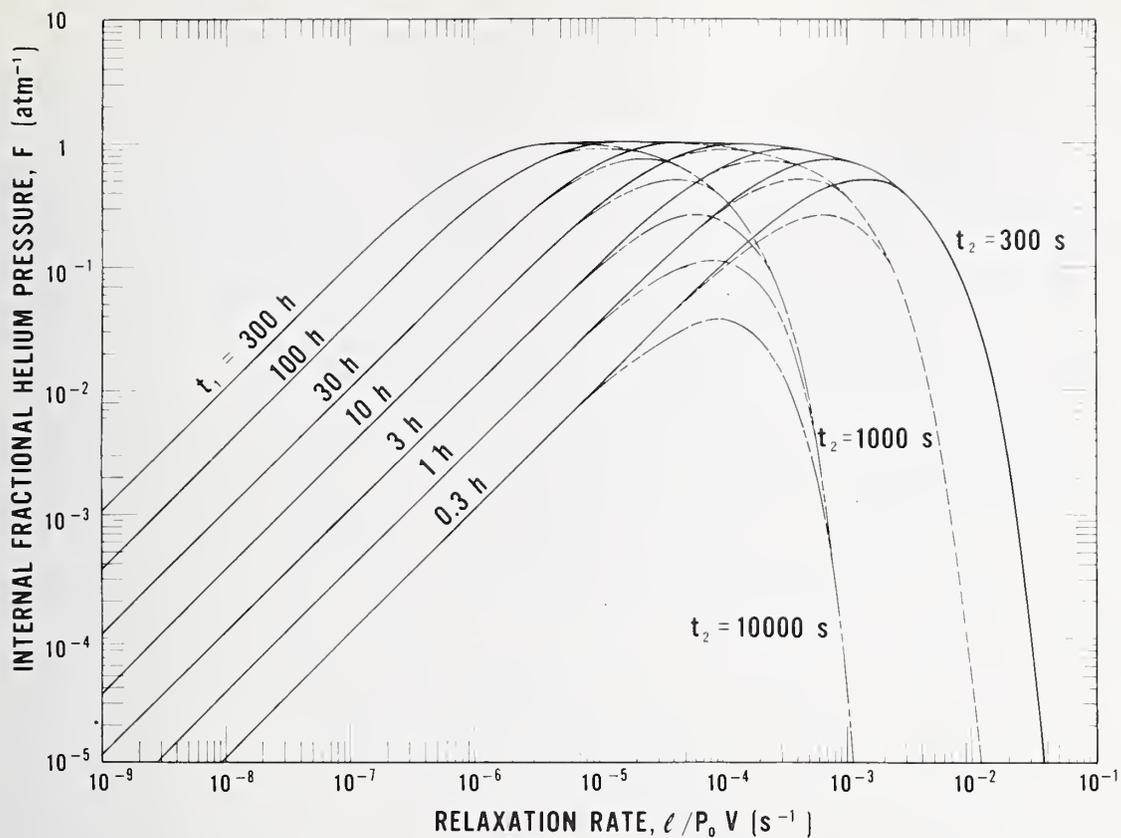


Figure 1. Internal fractional helium pressure versus relaxation rate for different pressurization times,  $t_1$ , and times between pressurization and measurement,  $t_2$ .

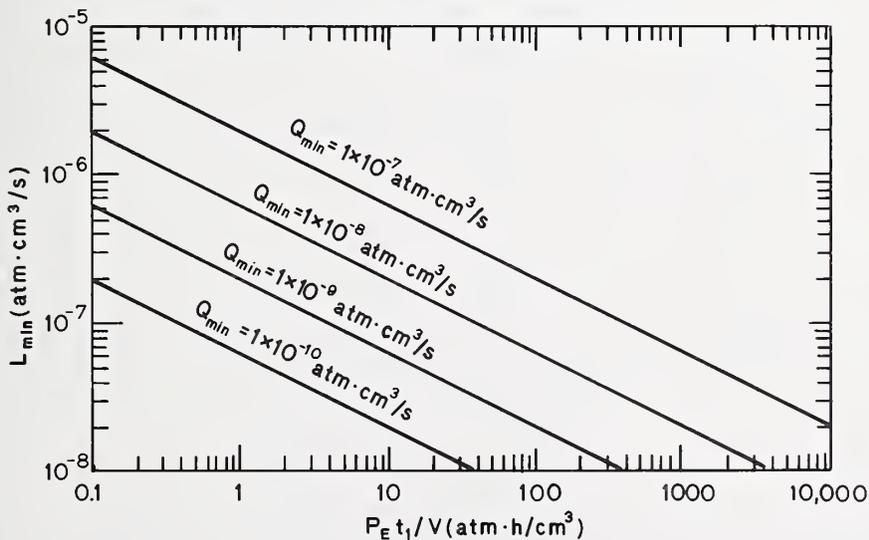


Figure 2. Determination of the minimum detectable leak rate for air.

values of relaxation rate below about  $10^{-5} \text{ s}^{-1}$ , as can be confirmed from figure 1. The curves in figure 2 become less accurate on the right-hand portion of the graph for increasing values of  $Q_{\min}$ , the minimum detectable signal of the leak detector, because of the assumption that there is no dependence on  $t_2$ .

In determining the maximum leak rate from figure 3, the curves include no dependence on  $t_1$ . Hence it is assumed that the relaxation rate (leak rate) is large enough such that this is the case, that is, the first exponential term in eq (1) is essentially zero. On the other hand, the assumption of molecular flow becomes less valid as the leak rate increases in the range of  $10^{-5} \text{ atm}\cdot\text{cm}^3/\text{s}$ . Therefore, the value obtained for  $L_{\max}$  should be considered as only an approximate one.

Consider an example as how figures 2 and 3 may be used. It should be noted first that the minimum detectable signal of the leak detector,  $Q_{\min}$ , is not set by the manufacturer's specifications. Rather, it is determined by noise levels and thresholds observed on the plant floor for a given package type. Therefore, consider that a clean ambient exists in the plant and sorption effects are small so that a threshold for helium of about  $5 \times 10^{-10} \text{ atm}\cdot\text{cm}^3/\text{s}$  is observed. Assume that a leak can readily be determined when the reading is twice the background so that  $Q_{\min} = 10^{-9} \text{ atm}\cdot\text{cm}^3/\text{s}$ . If  $P_E = 5 \text{ atm}$  and  $t_2 = 1000 \text{ s}$ , what is the pressurization time,  $t_1$ , required to detect a minimum air leak  $L_{\min} = 10^{-8} \text{ atm}\cdot\text{cm}^3/\text{s}$  (which one may wish to establish as a reject level) and what is the maximum leak rate one will be able to detect for these measurement conditions? From figure 2 we can see that for the values given for  $L_{\min}$  and  $Q_{\min}$ , a value for  $P_E t_1/V$  of  $400 \text{ s}^{-1}$  is immediately obtained, from which  $t_1 = 0.8 \text{ h}$ . If the leak rate rejection level were to be relaxed from  $10^{-8}$  to  $10^{-7} \text{ atm}\cdot\text{cm}^3/\text{s}$ , the value for  $P_E t_1/V$  and hence  $t_1$  would be reduced by a hundred and result in a great saving in test time. Note, however, that as the interior volume of the package increases, the pressurization time increases. For the case just considered, with  $L_{\min} =$

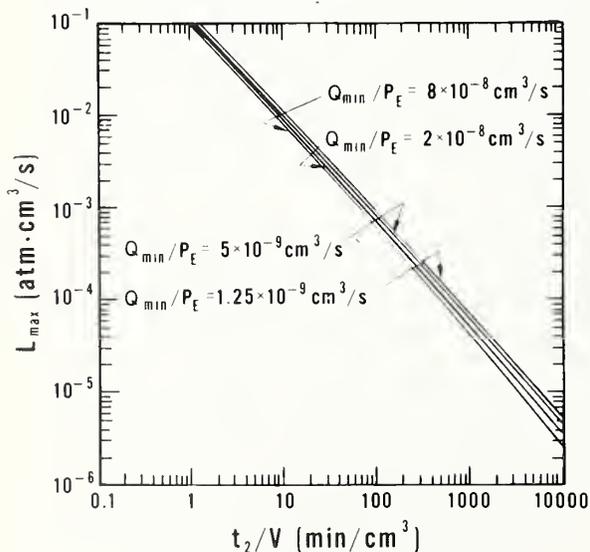


Figure 3. Determination of the maximum leak rate for air.

$10^{-8} \text{ atm}\cdot\text{cm}^3/\text{s}$ , if the interior volume is increased from  $0.1$  to  $1.0 \text{ cm}^3$  the pressurization time increases from  $0.8$  to  $80 \text{ h}$ ! To obtain the maximum detectable leak rate,  $L_{\max}$ , we use figure 3. For  $t_2 = 1000 \text{ s}$  ( $16.7 \text{ min}$ ), the value for  $t_2/V$  is  $\approx 1670 \text{ min}/\text{cm}^3$ .  $Q_{\min}/P_E$  is  $2 \times 10^{-10}$ ; by extrapolating from the values provided in figure 3, one obtains a value for  $L_{\max}$  of about  $5 \times 10^{-5} \text{ atm}\cdot\text{cm}^3/\text{s}$ .

The other fine leak test method in wide use is the radioisotope method. It involves pressurizing the package in a mixture of air and radioactive isotope krypton-85 gas and afterwards measuring,

with a scintillation crystal, the gamma radiation from the krypton gas that has entered through the leak and is still inside the package. Because the method only requires that the gas that has entered be measured, a smaller minimum detectable leak rate can be measured than with the helium method, for the same pressurization. Care must be exercised to assure that the measurement does not include radiation from any krypton-85 gas which may have been adsorbed on the package surface during the pressurization step.

The equation that is traditionally used to relate the parameters of the test is

$$R = KST \frac{L}{P_0^2} (P_2^2 - P_1^2) \quad (3)$$

where  $R$  = count rate,  $\text{min}^{-1}$ ,

$K$  = counting efficiency of the scintillation crystal for krypton-85 inside the package,  $\text{counts/min} \cdot \mu\text{Ci}$ ,

$S$  = specific activity of the krypton-85 gas,  $\mu\text{Ci/atm} \cdot \text{cm}^3$ ,

$T$  = pressurization time, s,

$L$  = leak rate,  $\text{atm} \cdot \text{cm}^3/\text{s}$ ,

$P_0$  = package ambient pressure, atm,

$P_2$  = pressure during pressurization, atm, and

$P_1$  = initial internal package pressure, atm.

The reason for the relative simplicity of this equation is not because the actual gas transport is any simpler than for the helium leak test method. Rather, it is only because more approximations have been made. First of all, this equation was developed using a laminar flow model for the gas entry into the package interior. Such a model is more appropriate for the gross leak range than for the fine leak range where the method is usually used. Also, no account is made for gas escape or for large internal pressure changes — that is, there is no specification of the time after pressurization that the measurement should be made (or dwell time) and there is no volume effect included. Thus, the method must have strict restrictions on the pressurization time and on the dwell time to obtain reproducible results.

Consider some examples in the use of the radioisotope test. Suppose we wish to find  $T$  if our leak rate reject level is  $L = 10^{-8} \text{ atm} \cdot \text{cm}^3/\text{s}$ . Suppose further that the specific activity is  $200 \mu\text{Ci/atm} \cdot \text{cm}^3$  and the counting efficiency is about  $15,000 \text{ counts/min} \cdot \mu\text{Ci}$ . Select a count rate above background of  $1000/\text{min}$  as  $R$  to indicate a leak rate  $L$  of  $10^{-8} \text{ atm} \cdot \text{cm}^3/\text{s}$ . For a pressurization of  $5 \text{ atm}$ , the pressurization time becomes  $1389 \text{ s}$  ( $23 \text{ min}$ ). If we, in fact, test a group of packages in this way, we might have some packages in the group with a leak rate as large as  $10^{-4} \text{ atm} \cdot \text{cm}^3/\text{s}$ . Because the count rate is  $10^3/\text{min}$  for packages with a leak rate of  $10^{-8} \text{ atm} \cdot \text{cm}^3/\text{s}$ , the count rate will be  $10^7/\text{min}$  for a package with a leak rate of  $10^{-4} \text{ atm} \cdot \text{cm}^3/\text{s}$  for short dwell times. But commercial equipment is usually limited to measuring only  $10^5/\text{min}$ , therefore only two decades of leak rates can be measured

per test if  $R = 10^3/\text{min}$ . The packages with large leaks will have too much radioactivity to continue testing. The proper test procedure for such equipment is to test for the larger leak rates first; for example, test for  $L_{\text{min}} = 10^{-6} \text{ atm}\cdot\text{cm}^3/\text{s}$  and range to a leak rate of  $10^{-4} \text{ atm}\cdot\text{cm}^3/\text{s}$ , and then follow with tests for smaller  $L_{\text{min}}$ .

An additional aspect must be considered when testing packages with large internal volumes ( $\geq 1 \text{ cm}^3$ ). In this case, testing for  $L_{\text{min}} = 10^{-6} \text{ atm}\cdot\text{cm}^3/\text{s}$  could still leave some packages with too much radioactivity. Thus, a prior test for  $L_{\text{min}} = 10^{-4}$  (e.g., at  $P_2 = 1 \text{ atm}$  and  $T = 10 \text{ s}$ ) might be used.

As a final word about the helium and radioisotope methods, it should be reiterated that they are not completely effective and procedures for them are still evolving. Work is still continuing to understand the effects of many variables and to determine the accuracy and precision of the methods. The equations used are not accurate but are workable approximations to be used under appropriate conditions dictated by experience.

### 3.11 Pacemaker Leads — A Physician's View

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From the clinician's point of view, fracture of lead wires is the fourth most important problem encountered with pacemaker implantation, ranking behind battery longevity, transvenous electrode dislodgement, and random electronic failure.

According to a recent survey<sup>1</sup> of pacing practices in the United States, 93 percent of pacemakers are inserted by the transvenous technique in which the electrode is inserted into the inner surface of the right ventricle through one of several veins in the neck or shoulder. Important procedures in this technique include establishing excellent contact between the electrode and the endocardium, measuring pacing thresholds and the amplitude of the intracardiac electrogram (both of which must be optimal for adequately long-term pacing function), fixing the lead wire to the vein, and positioning the pulse generator in a comfortable position on the anterior chest wall. Failure to observe correct practices in these procedures can lead to subsequent wire fractures. The essential precautions to be observed are careful handling of the wire, proper fixation of the lead to the tissues (tightly enough so that it will not withdraw, yet loosely enough so that the insulation will not be cut by the ligature), and avoidance of bends in the lead and of conditions where a fulcrum effect could eventually result in lead fracture.

A review of 689 pacemaker reoperations over the past 5 years revealed that leading causes for pacemaker replacement were battery exhaustion, election by the

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<sup>1</sup>Parsonnet, V., Manhardt, M., and Parsonnet, M., Survey of Pacing in the United States 1975, presented at the Vth International Symposium on Cardiac Pacing, Tokyo, March 1976.

patient or physician, component failure, and wire fractures. These were followed closely behind by threshold problems and a variety of miscellaneous less common disorders. The observed incidence of wire fractures (7 percent) was considerably higher than reported in the national survey, where a figure of 1 percent was reported. It is hard to explain this difference, except that there were shorter observation periods in most of the other reporting clinics.

An interesting observation related to the time of the wire fracture is that the age of the wire had little to do with the incidence of fracture. The wires broke at a rate of about 2 percent a year irrespective of age. A particular analysis of 100 patients who survived for more than 3 years revealed that 78 percent required another operation within that time. Although many of these operations were for battery exhaustion, 30 percent of the patients required operations for something *other* than battery failure before 3 years had elapsed, and about one third of these were for wire fractures. If fractures continue to occur at the present observed rate, between 1 and 2 percent a year, one would expect that 10 to 20 percent of pacemakers would fail within 10 years from this cause alone, and 20 to 40 percent in 20 years. This would almost negate the advantages gained by the use of long-life sources.

Fracture of a wire usually occurs suddenly and typically produces sudden cessation of pacing, although there are instances where pacing may be intermittent. Sudden cessation of pacing may lead to Stokes-Adams seizures or the death of the patient. It is pertinent, therefore, to discuss the chance of a fatality should a pacemaker stop functioning abruptly. In the national survey mentioned above, there were approximately 40,000 patients covered by 169 reporting centers. Approximately half of these patients had died during the reporting period, mostly from non-pacer related causes. Specifically, 25 documented cases were reported where death was due to pacemaker failure. Thus, about 0.1 percent of the deaths was related to pacemaker failure. Of these, 13 were due to runaway rates and the remainder due to a mixture of problems, 3 of which were wire failures. The *infrequency of sudden deaths* is readily understandable considering that most patients with implanted pacemakers do not have fixed complete heart block. In the last 100 consecutive cases, only 4 percent of our patients had fixed complete heart block, and only 15 percent had fixed or intermittent block. Furthermore, it is known that most of these patients often have periods where their rhythm may be normal. Therefore, in the great majority of patients the *status quo ante* will return when a pacemaker stops functioning and that status is a living condition. Therefore, on both theoretical and factual grounds the danger of death due to pacemaker failure is remote, and one therefore questions much of the public hysteria on this matter.

Wire fractures had at one time been caused by a variety of problems that are no longer seen. Examples of problems are stiffening wires left inside of the helical coil, poor welds between the electrode lead wire and the electrode, poorly constructed

splices of previous breaks, and the use of inadequate materials. In recent days, fractures are more commonly seen at the point of fixation of the electrode to the vein, either at a tight ligature or at a "butterfly" flange that does not have a strain-relieving taper at either end (see figure 1). Fractures at the pulse generator connector are also relatively frequent. These causes of fractures can be eliminated by using a tapered "butterfly" and by wrapping the pulse generator in a Dacron<sup>2</sup> pouch that immobilizes it and prevents the fulcrum effect at the connector. We have yet to see a fracture at the connector or at the "butterfly" since making these modifications.

Fractures continue to occur in the free wire, and these are usually of unknown cause. Unfortunately, fragments of broken wire are rarely sent back to the manufacturer by the physician user and therefore the manufacturer is neither aware of the incidence of wire fractures nor aware of the causes. These facts about wire fractures call attention to the need for more information on the causes of wire fracture and the development of a lead that is more resistant to fatigue.

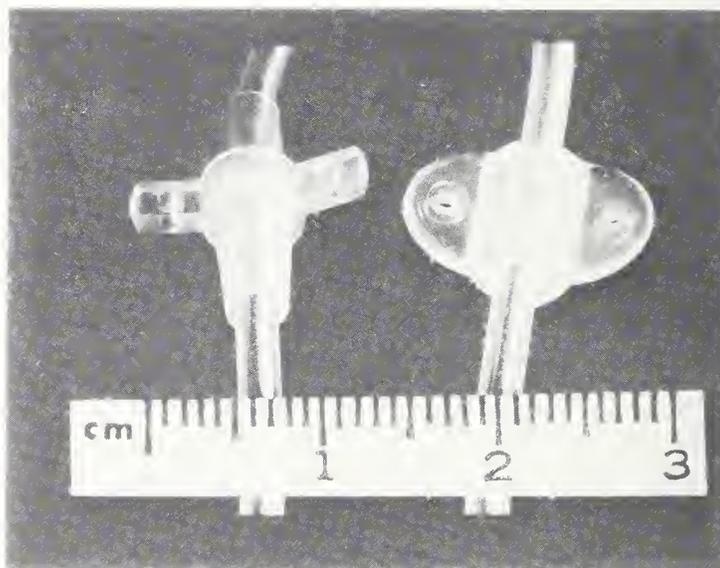


Figure 1. Butterfly flange with a strain-relieving taper (left) and one without (right).

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<sup>2</sup>See disclaimer, footnote 1, p. 10.

### 3.12 The Performance of Implantable Pacing Leads

#### — A Status Report

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The average time between surgical operations for the cardiac pacer patient has been increasing over the past fifteen years. This has been made possible through the use of improved power sources, more reliable and more efficient electronic circuits, better construction methods and encapsulation techniques, and refinements in quality control. Pulse generator service lives of ten years or more are becoming quite probable. More attention must now be focused on the longevity of connecting leads and electrodes which in the past have performed adequately in comparison with the pulse generator.

Approximately 150,000 new leads are implanted worldwide each year. This figure is based on data which was reported<sup>1</sup> for 1975 and is shown in table 1.

TABLE 1

#### NEW LEADS IMPLANTED IN 1975

	Population Represented (10 <sup>6</sup> )	Estimated Implant Rate Per 10 <sup>6</sup>	Total Population (10 <sup>6</sup> )	Total Number of Implants Per Year (10 <sup>3</sup> )
U.S. (N.J.)	7	320	220	70.0
Canada	22.7	110	22.7	2.5
Europe	243.8	114	469*	53.5
South America	8.5	27	220	5.9
Australia	13.5	50	13.5	0.7
Far East	117	14	117	1.6

\* Not including U.S.S.R.

Estimated Total New Leads: 134,200 Per Year

For the World (Estimated): 150,000 Per Year

<sup>1</sup>14th International Symposium on Cardiac Pacing, Abstracts of Free Communications with World Survey on Long-Term Follow-Up of Cardiac Pacing, pp. 97-156, Tokyo, March 14 to 18, 1976. Domestic pacemaker data are available only for the state of New Jersey; data estimates for the United States are based on extrapolations of the New Jersey data.

The histogram in figure 1 shows the age distribution of patients in five geographic regions at the time of their first implantation. The distributions for each of the five regions are similar except for South America where implants are performed on a larger percentage of young patients, presumably due to the endemic Chagas disease peculiar to this region.

The following figures should provide some perspective for the performance to be expected from a lead system designed to be implanted: Based on the estimated 150,000 new implant patients in 1975, as many as 22,500 of those might be alive in 1995 and about 75,000 could be alive in 1985. These figures are based on the assumption, probably overly optimistic, that the survival probability of a pacemaker patient is the same as the general population. Standard actuarial tables were used to determine what percentage of a group of patients with new implants are expected to survive a given period. Table 2 provides the estimated survival data for 5, 10, and 20 years, and table 3 provides some actual survival data reported for the 5- and 10-year periods which ended prior to 1975.

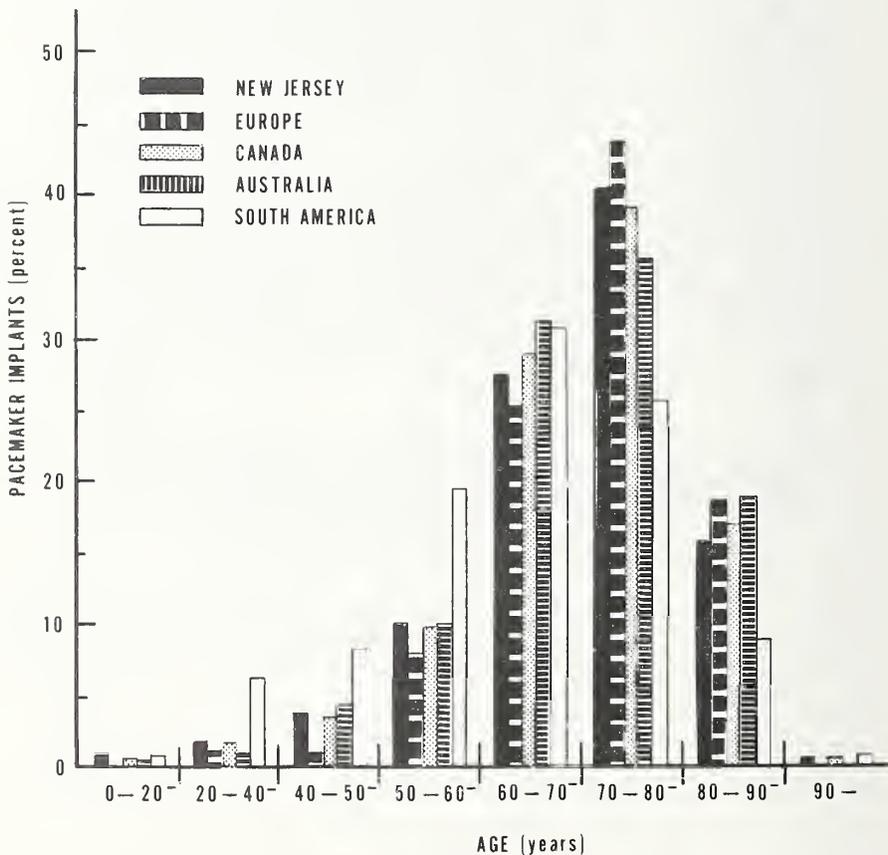


Figure 1. Age distribution of patients in five geographic regions at the time of their first pacemaker implantation.

TABLE 2

## Estimated Survival Rates of New Implant Patients

Age at Implant (years)	Patient Age Distribution at Implant (%)	5-Year Survival Estimate (%)		10-Year Survival Estimate (%)		20-Year Survival Estimate (%)	
		Survival Probability	Surviving Patient Distribution	Survival Probability	Surviving Patient Distribution	Survival Probability	Surviving Patient Distribution
0-20	0.9	99.3	0.9	99.1	0.9	98.1	0.9
20-40	1.8	99.3	1.8	97.4	1.8	94.1	1.7
40-50	3.8	98.3	3.7	88.9	3.4	81.7	3.1
50-60	10.0	96.0	9.6	87.2	8.7	59.3	5.9
60-70	27.2	90.7	24.7	71.8	19.5	12.8	3.5
70-80	40.2	78.8	31.7	37.2	15.0	?	
80-90	15.5	52.9	8.5	?	-	?	
90-	0.6	?	-	?	-	?	
Total	100		80.9		49.3		15.1

TABLE 3

## Actual Survival Rates Reported

Area	Survivors (%)	
	After 5 Years	After 10 Years
New Jersey	56	40
France	50	-
Canada	75	-
Japan	81	-
South Africa	71	-
Portugal	51	-
West Germany	56	-
Netherlands	58	-
Hong Kong	50	-

Lead related problems may be divided into the five categories listed in table 4. Many of these problems may be prevented through more fatigue and corrosion resistant materials, redundancy in the design, and improved fabrication techniques. Past performance of leads points to areas where design improvements are desirable. These include the prevention of lead dislodgement through the use of mechanical attachment or tissue growth stimulation to increase anchoring, and the use of improved materials and designs to reduce flexing stresses.

Proof of improved performance must be obtained through accelerated test methods. The tests must simulate the environmental aspects of an actual implant as closely as possible. Special emphasis must be given to fatigue from repeated bending around a small radius, and to galvanic, stress, and crevice corrosion aggravated by pulsatile current loading and stretching. These tests are very time consuming. For example, if the loss of material through corrosion must not exceed 5 mils (125  $\mu\text{m}$ ) in 20 years, then the tests should run for at least a year.<sup>2</sup> In order to prevent tissue reaction due to metal ion penetration, the corrosion rate must be less than 0.01 mils (0.25  $\mu\text{m}$ ) per year.<sup>3</sup> More than 20 years of testing may be necessary to establish this level of corrosion resistance.<sup>2</sup> Intelligent use of existing engineering data, however, can shorten the necessary time for gathering test data.

TABLE 4

Lead-Related Problems Listed with Causes

<u>Material:</u>	<u>Design:</u>
Fractured Conductor	Too Stiff
Broken Insulation	Too Flexible
Corrosion	Mechanical Mismatch
Erosion	Bad Joints
<u>Fabrication:</u>	Poor Connection to Pacer Generator
High Internal Resistance Connection	Improper Electrode Material and Shape
Poor Contact with Pacer Generator	High-Resistance Wire
Contamination	Excessive Polarization
<u>Surgical:</u>	EMI
-Dislodgement	<u>Biological:</u>
-Poor Electrode Site	-Excessive Reaction (Exit or Entry Block)
-Perforation	-Valve Insufficiency
-Improper Connection to Pacer Generator	-Thrombi
-Sharp or Constricted Venous Entry	-Growth Induced Stress
-Poor "Looping"	-Twiddling

<sup>2</sup>Fontana, M. G., and Green, N. D., *Corrosion Engineering*, McGraw Hill, New York (1967) p. 135.

<sup>3</sup>*ibid*, p. 289.

At this time, Pt-Ir, Elgiloy, MP35, and Stellite are commonly used lead and electrode materials.<sup>4</sup> Titanium for leads and carbon for electrodes are among the materials presently receiving consideration. Improvements are expected in lead insulators which are more biocompatible and more moisture resistant than, for example, Silastic<sup>4</sup>, which is widely used.

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<sup>4</sup>See disclaimer, footnote 1, p. 10.

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#### ACKNOWLEDGMENT

The full cooperation of the speakers in the preparation of this report is sincerely appreciated, as is the assistance of W. M. Bullis of this laboratory. The camera-ready copy of the report was typed and composed by E. Jane Walters with her usual high degree of efficiency and competence.

## APPENDIX

### Workshop Program

— Monday, July 19 —

#### INTRODUCTION TO WORKSHOP

Harry A. Schafft, National Bureau of Standards

#### SESSION I: RELIABILITY ASSURANCE

##### Presentations

*Process Validation Wafers for Use in Procuring Reliable Custom Integrated Circuit Chips*

Martin G. Buehler, National Bureau of Standards

*High Reliability Microcircuit Procurement Controls*

W. J. Kitchen, Jr. and Terrence H. Brown, National Security Agency, Ft. Meade, MD

*Mechanisms of Dendritic Growth*

Robert P. Frankenthal, Bell Laboratories, Murray Hill, NJ

*Use of Epoxies in Hybrid Microelectronics*

Ralph F. Redemske, Teledyne Microelectronics, Los Angeles, CA

##### Group Discussions\*

#### SESSION II: A. BATTERIES, B. RELIABILITY PREDICTION AND COMPARISON

##### Presentations

*Microcalorimetric Study of Pacemakers and Batteries*

Edward J. Prosen and Jennifer C. Colbert, National Bureau of Standards

*Statistical Methods for Estimating Longevity of Pacemaker Batteries*

Douglas J. Gerrard, Medtronic, Inc., Minneapolis, MN

*Applications and Pitfalls of Pacemaker Reliability Prediction*

John Maness and Stanley Kus, Illinois Institute of Technology Research Institute, Chicago, IL

*A Reliability Comparison of Semiconductor and Microcircuit Technologies*

Harold A. Lauffenburger, Reliability Analysis Center, Griffiss Air Force Base, NY

##### Group Discussions\*

#### EVENING SESSION ON PACEMAKER BATTERIES

Chairman: Boone Owens, Medtronic, Inc., Minneapolis, MN

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##### \*Discussion Group Chairmen:

Robert D. Fischer, Custom Devices, Phoenix, AZ

Jerome Fishel, Circuit Technology, Inc., Farmingdale, NY

Randy Veale, Food and Drug Administration, Silver Spring, MD

Robert I. Seace, National Bureau of Standards, Washington, DC

— Tuesday, July 20 —

SESSION III: A. HERMETICITY, B. PACEMAKER LEADS

Presentations

*Moisture Measurements, Leak Rate, and Reliability - A Status Report*  
Robert Sulouff, Martin Marietta Aerospace, Orlando, FL

*The Fundamentals of Leak Testing for Cardiac Pacemakers*  
Stanley Ruthberg, National Bureau of Standards

*Pacemaker Leads - A Physician's View*  
Victor Parsonnet, M.D., Newark Beth Israel Hospital, Newark, NJ

*The Performance of Implantable Pacing Leads - A Status Report*  
Peter P. Tarjan, Cordis Corporation, Miami, FL

Group Discussions\*

SESSION IV: SPEAKERS' REPORTS AND OPEN DISCUSSION

ADJOURN

U.S. DEPT. OF COMM. BIBLIOGRAPHIC DATA SHEET	1. PUBLICATION OR REPORT NO. SP 400-42	2. Gov't Accession No.	3. Recipient's Accession No.
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16. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.)  Summaries are presented of 12 invited talks on the following topics: the procurement and assurance of high reliability electronic parts, leak rate and moisture measurements, pacemaker batteries, and pacemaker leads. The workshop, second in a series, was held in response to strong interest expressed by the pacemaker community to address technical questions relevant to the enhancement and assurance of cardiac pacemaker reliability. Discussed at the workshop were a process validation wafer concept for assuring process uniformity in device chips; screen tests for assuring reliable electronic parts; reliability prediction; reliability comparison of semiconductor technologies; mechanisms of short-circuiting dendritic growths; details of helium and radioisotope leak test methods; a study to correlate package leak rates, as measured with test gases, and actual moisture infusion; battery life prediction; microcalorimetric measurements to nondestructively evaluate batteries for pacemakers; and an engineer's and a physician's view of the present status of pacemaker leads.			
17. KEY WORDS (six to twelve entries; alphabetical order; capitalize only the first letter of the first key word unless a proper name; separated by semicolons)  Batteries; cardiac pacemakers; hermeticity; hybrid devices; leak testing; measurement technology; microcalorimetry; pacemaker leads; process control; reliability; semiconductor devices; screen tests.			
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