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AN APPROACH TO THE RELIABILITY OF IMPLANTABLE LITHIUM BATTERIES

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Summary

The reliability process for implantable lithium batteries begins with the cell development and design. After the design period and prototype production, a complete qualification program is performed in which a new cell design is subjected to environmental, safety, abuse, and performance testing. Early production of new cell designs includes significant sampling and testing to spot quality problems. Incoming inspection, in-process inspections, final acceptance testing, and routine destructive analysis are all part of the overall quality program. Complete documentation and traceability is conducted. The final component of the quality program is the life-test sampling, in which significant running samples of all cell models are subjected to conditions approximating the real-time use cycle.

Introduction

The design and manufacture of implantable batteries present significant challenges to the developer and producer of such cells. Implantable batteries must be safe and reliable. The long-term performance of implantable batteries must be predictable from shorter-term accelerated tests. The interaction of device and cell must be well-understood. The approach to cell end-of-life must be predictable and readily detected by the electronic circuitry of the device.

Lithium batteries have been used as power sources for implantable devices since 1972. Today all cardiac pacemakers use lithium power sources, and of these approximately 90% use the lithium/iodine–poly(vinylpyridine) system. This system has demonstrated an excellent record of reliability and its long-term behavior is fairly well-understood at this point because of the almost 16 years of real-time data which has been amassed on this system.

With the advent of newer implantable devices such as neurostimulators, drug delivery systems, and the implantable defibrillator, has come the need to develop and characterize alternative chemical systems which can deliver the required heavier currents demanded of these devices. Both soluble

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cathode systems and solid cathode/liquid organic electrolyte systems have been developed and used to power these devices [1 - 3]. It has been necessary to develop methods of characterizing these newer battery systems to insure that the long-term reliable performance requirements of implantable power sources can be met.

The reliability program begins in the design phase of a new cell development. A rigorous characterization and qualification program is established to determine cell performance and safety. Vendor qualification and control insures the suitability of battery components. The manufacturing process is set up with frequent inspection and testing steps. Complete traceability of all components and operations is maintained. Final inspection and electrical testing assures compliance with in-house and customer specifications. A program of life-testing of a running sample of production units provides long-term data which can be compared with accelerated test data.

The quality system used to control the production of implantable batteries is patterned after the requirements set forth in the *Good Manufacturing Practices* developed and issued by the United States Food and Drug Administration [4]. These guidelines require that appropriate facilities, organization, personnel, procedures, and controls, are in use in the manufacturing process. The guidelines also demand stringent documentation and design control.

The following sections of this paper will present the steps taken by this company to insure the reliability and quality of implantable batteries. Special emphasis will be given to the development and characterization of the lithium/silver vanadium oxide (SVO) battery system which has been developed to power the implantable defibrillator. Since this was a new chemical system designed to meet requirements rather different and more stringent from those of the cardiac pacemaker, a rather more complicated characterization and qualification program was developed. This system will be presented in the following sections of the paper.

Cell design and qualification

The design and qualification of new lithium/iodine pacemaker batteries has become a rather straightforward process since fundamental questions, such as materials compatibility and general cell performance, have largely been answered. However, any new cell design features, *i.e.*, alternative methods of applying anode coating or alternative seal designs, are carefully tested and qualified by the reliability group before being implemented into implantable cells. Each new cell model undergoes a complete qualification test regime which includes accelerated discharge, shock and vibration, thermal cycling, and exposure to high temperatures and pressures [5].

The design and qualification testing of the lithium/SVO defibrillator batteries required considerable effort and testing. A battery for the implantable defibrillator must be capable of providing pulses of 2.0 A current at voltages above 2.0 V for ten s. These pulses must be delivered over

a background current of a few microamperes which powers the sensing circuitry of the device. There can be no appreciable voltage delay, and the self-discharge must be low enough to provide years of service. A three-year development and characterization program was completed before the first model was qualified for implantable use. The development program involved the construction and testing of hundreds of batteries as well as extensive chemical characterization of the cathode material itself. The optimum cathode composition ($Ag_2V_4O_{11}$) for cell performance was determined by titration of samples of material with varying silver contents with *n*-butyllithium, and subsequent discharge testing of cells made from these materials [6].

Considerable effort was expended in choosing the correct cell materials for compatibility. Electrochemical corrosion techniques were used to screen materials for use in the batteries. The results of these tests were confirmed by an extensive series of elevated temperature tests of actual batteries using candidate materials. The cells were subsequently destructively analyzed and the components examined in the scanning electron microscope for any signs of corrosion. More tests of cells at body temperature are in progress. Corrosion-resistant glass was chosen for the glass-to-metal seal. As a redundant measure, the glass is also coated with a polymeric material which prevents, or retards, contact of the glass with the organic electrolyte.

Extensive safety testing was performed throughout the design process. Short circuit testing, crush testing, forced overdischarge, and recharge testing, were done to demonstrate the safety of the cells. A more formalized set of safety tests was conducted in the qualification test phase of the cell development program discussed below.

Self-discharge of the system was evaluated by microcalorimetry and by discharging test cells at a variety of current drains before and after storage [7]. The self-discharge of the system is estimated at less than 2% per year.

The formal qualification procedure involved the testing of defibrillator cells in a variety of standard and abusive safety and environmental tests. The standard tests include the following:

- Thermal cycling from 70 °C to −40 °C with 1 min transition time
- High pressure testing at 90 and 120 p.s.i.
- Low pressure testing under vacuum equivalent to 4500, 12 030 and 15 000 meters above sea-level
- Low and high temperature exposure
- Short circuit at room temperature and at 37 °C
- Forced overdischarge at the $C/10$ rate, where C is the cell capacity
- Forced overdischarge of a depleted cell by a fresh cell
- Shock testing with a 1000 g force
- Vibration testing at frequencies ranging from 5 to 5000 Hz, peak acceleration 5 *g*.

Cells are subjected to these tests in three states of discharge — beginning of life, half-depleted, and fully depleted. After each test the cells are visually inspected, measured for dimensional changes, examined by X-radiography.

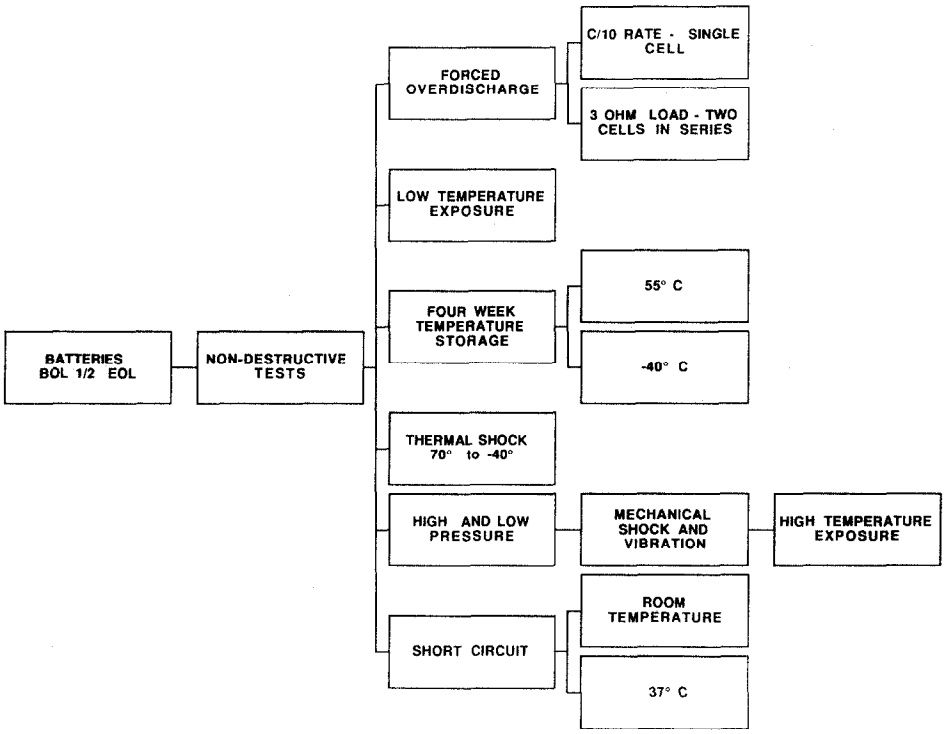

Fig. 1. Standard qualification test protocol for the defibrillator battery.

and submitted to pulse testing. Often multiple tests are performed on the same cells in order to evaluate the effects of combining several tests. Figure 1 shows a diagram of the test procedure. None of the above tests led to cell leakage, rupture, or the creation of an internal short circuit. Short-circuit testing causes cells to swell, and results in a peak temperature rise of approximately 100 °C in fresh cells.

Abusive testing is conducted to assess the ability of the cell to withstand very abusive conditions and to demonstrate certain hazards associated with such abuses. Tests include crushing until internal short-circuiting is induced (which does not cause cells to explode), recharging, forced overdischarge under a 2 A current at a maximum voltage of 5 V (which can cause cell rupture in the case of beginning-of-life cells), incineration (which normally causes cells to explode), impact testing to assess shock sensitivity, and slow dent and puncture. Figure 2 shows a diagram of the abusive test procedure.

The qualification program also involves verification of cell capacity by accelerated discharge testing. Cells are tested under a pulse test regime described below. Capacity is determined for fresh cells and for cells after exposure to high and low temperatures. The results of the qualification testing are summarized in a report which is supplied to potential users of the cell.

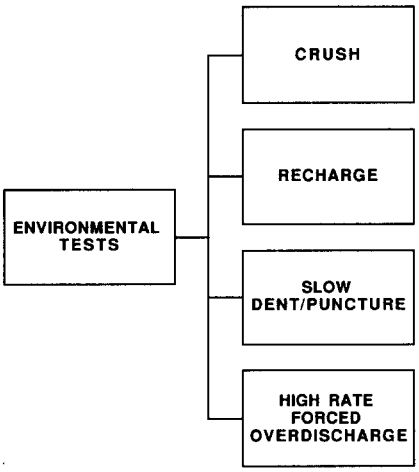

Fig. 2. Abusive test protocol for the defibrillator battery.

After successful completion of the qualification program, shipment of implantable-grade production can begin. A complete print package, process specifications, work instruction, and quality control instructions are issued. Configuration control is maintained by a strict Engineering Change Order (ECO) system. No changes to either processes or components may be made without the written approval of authorized representatives of production, purchasing, design engineering, quality control, manufacturing engineering, product assurance, and research. Significant changes in either components or processes must be subjected to a qualification procedure by the reliability group of the Product Assurance division.

In-process control and testing

In-process control begins with an extensive vendor control/incoming inspection program. Vendors must be qualified by the reliability group. Qualification samples of components supplied by new vendors are subjected to inspection, documentation, materials testing and, in the case of critical components such as glass-to-metal seals, a qualification program designed to subject the parts to standard and abusive test conditions. All incoming parts go through an incoming inspection regime where they are measured and inspected according to a predetermined sampling plan. Records of vendor performance are maintained. Each new lot of components is assigned a lot number and is provided with a "lot traveler" which documents all operations and inspections performed on the lot and is eventually traceable to the serial numbers of each battery containing the component. Audits of vendor facilities may be conducted if necessary to assure compliance with standards.

During the manufacturing process all operations are documented on lot travelers and the "device history record", which allows complete traceability

to the serial number of each battery. Inspection of subassemblies is conducted and documented. Batteries are subjected to 100% helium leak testing at two points in the construction process — once as "prepour" subassemblies and again as finished batteries.

A running sample of defibrillator batteries is taken for routine accelerated testing. Cells are placed under open circuit conditions. Every thirty minutes test cells are subjected to a pulse train consisting of four, 10 s pulses. There is a 15 s interval between each such pulse. The pulse amplitude can be varied, but it is set at 2 A for the standard test. All testing is conducted at 37 °C. A computerized data collection system measures the voltage of the pulses and notes the minimum voltage for each pulse. The total capacity of the cell and the number of pulses delivered to a 2 V cutoff are determined.

For both lithium/iodine and lithium/SVO batteries, routine samples are taken and submitted for metallurgical evaluation of the welds. Cross sections of weld zones are prepared and examined microscopically for metallurgical structure and cracks. A further sample of 1% of all batteries is selected for routine destructive analysis in which quantitative ratings are assigned to predetermined attributes of cell construction.

The presence of defects in the destructive analysis requires corrective action and may lead to rejection of groups of batteries.

After basic battery construction is completed, X-rays of all cells are taken and kept as part of the permanent record. Cells are then ready for final electrical testing. Each battery undergoes a "burn-in" testing period to insure that initial electrical performance meets required standards. Lithium/iodine batteries undergo a 35 day electrical test under a 100 kΩ load at 37 °C. Voltage and impedance readings are taken five times during this period and must meet predetermined standards for acceptance. Lithium/SVO defibrillator batteries are subjected to a more complicated burn-in procedure in which the cell is subjected to a series of high-current pulses superimposed over an open-circuit background. Both the open-circuit voltages and the high-current pulse voltages must meet minimum standards. The burn-in period is 21 days.

After completion of the burn-in testing period the cell terminals are modified for specific customer requirements. Cells are then subjected to a final visual examination under a 10× microscope, and a final helium leak test is performed. Cells are then released for shipping after a final check of all documentation and build records, and a record is made of the final destination of each cell.

Backing up this quality system is an in-house auditing function. A full-time quality auditor, trained and certified in the requirements of the FDA's Good Manufacturing Practices, conducts audits of production, inspection, and documentation procedures on a random basis. The auditing process considers seven basic categories. These are: safety, materials, parts and subassemblies, compliance with written instructions, condition of equipment, documentation, drawings, and miscellaneous considerations such as training, working conditions, and environmental problems. A quantitative

"compliance index" is calculated for each audit, and monthly summaries of audit results are provided to upper management [8].

Estimation and verification of real-time performance

It is necessary to develop accelerated tests that can accurately predict the performance of batteries which are expected to perform over a several-year period. For obvious reasons it is particularly important to be able to model the approach to the cutoff voltage of the device. Implantable devices are designed to signal and communicate in some manner (usually telemetry) that the battery is nearing what is known as the "elective replacement voltage", and accurate knowledge of the amount of time remaining between the attainment of this voltage and device shutdown is critically important.

A well-understood and verified system of accelerated testing has been developed for lithium/iodine pacemaker batteries. This has been described in some detail in the literature [5]. The procedure involves discharging groups of batteries under each of eight different constant resistive loads. The loads correspond to currents significantly higher than those seen in pacemakers. The voltage data from these tests are converted to equivalent data at other constant resistive loads (corresponding to typical pacemaker conditions) by the equation:

$$V_2 = V_{oc} V_1 R_1 R_2 / [R_1 R_2 V_1 + R_1^2 (V_{oc} - V_1)], \quad (1)$$

where V_1 is the known voltage, V_2 is the unknown voltage, V_{oc} is the open circuit voltage, R_1 is the resistive load of the known voltage, and R_2 is the resistive load of the unknown voltage. A projected composite curve under a typical pacemaker load (140 kΩ) is generated by taking a weighted average of the "family of curves" generated at the accelerated test loads. A curve-fitting equation is then generated which, when taken with eqn. (1) above, allows the projected discharge curve to be generated at any desired discharge current.

Since lithium/SVO defibrillator batteries can operate efficiently at higher current drains, it is possible to determine cell capacity by discharging at current drains higher than those possible for lithium/iodine cells. A standard accelerated test has been developed for Li/SVO cells which tests the ability of the cell to provide high-current pulses over a background current. Cells are placed under open circuit conditions. Every 30 min test cells are subjected to a pulse train consisting of four, 10 s pulses. There is a 15 s interval between each such pulse. The pulse amplitude can be varied, but it is set at 2 A for the standard test. All testing is conducted at 37 °C. A computerized data collection system measures the voltage of the pulses and notes the minimum voltage for each pulse. The total capacity of the cell and the number of pulses delivered to a 2 V cutoff voltage are determined. Figure 3 shows the results of a typical experiment. The data shown in the Figure are for the Model 8512 cell, a rectangular, prismatic shape, of nominal

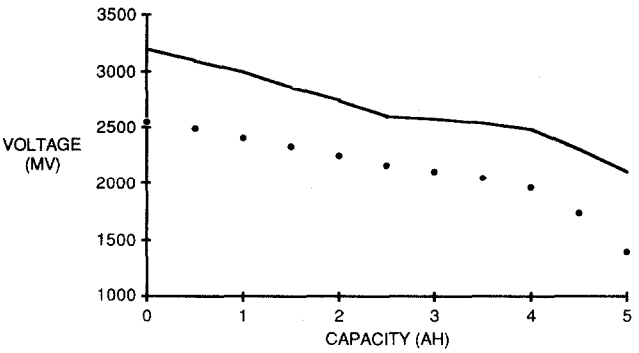

Fig. 3. Results of accelerated testing of the Model 8512 defibrillator battery.

dimensions 13.5 mm × 52 mm × 33 mm, and rated capacity 5.5 A h. This method alone is not effective in determining the shape of the voltage curve under the background current during the first part of the discharge curve, since significant polarization can occur immediately after the imposition of the four-pulse train. The shape of this curve was determined by experiments which allowed the cell's background voltage to "recover" to a value more typical of what would be seen in the actual use condition. The sloping nature of the discharge curve near the elective replacement voltage provides a useful indicator of the time remaining before the cutoff voltage is reached.

An important part of the reliability system is the maintenance of an extensive life-test sample. A running sample of batteries is placed on a life test program. When a new battery model is introduced, the sample size is 10%, and it gradually reduces to 1%. The 1% sampling rate is maintained throughout the production life of the cell. In the case of lithium/iodine pacemaker cells, the life-test sample is placed under a 100 kΩ constant resistive load at 37 °C. Voltage and impedance measurements are taken bimonthly, and a computer program selects and prints out the data for any cell whose voltage falls below a predetermined standard. Defibrillator batteries are subjected to two types of life tests. The first involves discharge under a constant resistive load corresponding to a typical background current for the device. In the second life test, cells are placed under the background load but are subjected once per month to a pulse train of four, 10 s pulses of 2 A with 15 s between pulses. This is designed to simulate a condition wherein a patient undergoes defibrillation once per month.

For lithium/iodine pacemaker batteries it is possible to compare the results of real-time tests with the accelerated test projections, since significant numbers of some smaller batteries have completed real-time discharge testing. Figures 4 and 5 present the results for the Model 761/15 cell. This cell was designed in 1978, and over 100 000 units were produced and implanted. The cell has a rectangular, prismatic shape with nominal dimensions 15 mm × 45 mm × 8.7 mm. The projected capacity is 1.3 A h. Over 2200 of these cells have now completed their discharge testing under 100 kΩ.

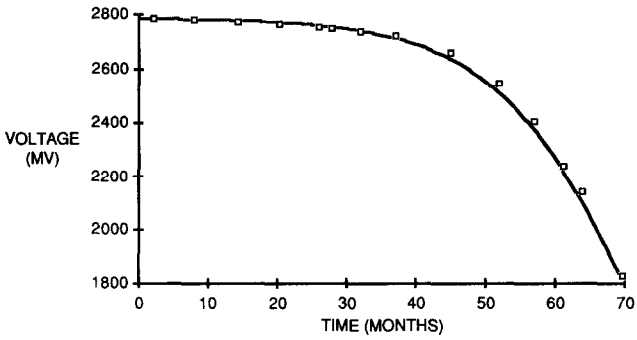

Fig. 4. A comparison of accelerated test predictions (——) and average real-time performance (□) of the Model 761/15 battery.

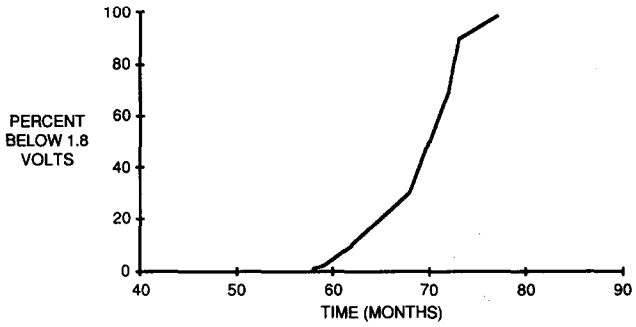

Fig. 5. Cumulative survival analysis of a group of 2200 Model 761/15 cells discharged under 100 kΩ load.

The solid line in Fig. 4 shows the predicted discharge curve which was obtained by the method described above. The white squares superimposed on this line show the average performance of the 2200 cells under 100 kΩ load. Figure 5 is a cumulative survival plot showing the percent. of cells with voltages above 1.8 V as a function of time on test. The average time to 1.8 V was 68 months.

Real-time data on defibrillator batteries are more limited, but some early implantable-grade batteries have now been on test for over one year. Figure 6 presents the results of testing to date for the Model 8512 battery. Shown as a function of time on test are the voltages under the background current (100 kΩ constant load) and the minimum voltage of the first pulse of the monthly 4-pulse train. A total of 12 batteries at various states of discharge are represented on this composite graph.

Conclusions

Implantable batteries present significant requirements of reliability, safety, and predictability of performance. The control of the reliability of

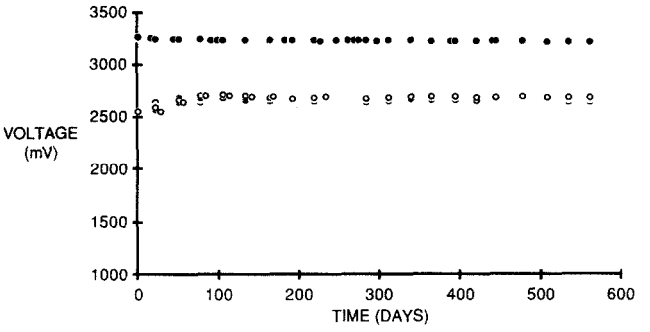

Fig. 6. Results of life testing of the Model 8512 defibrillator battery. Top curve is the background voltage (100 kΩ constant load), lower curve is the voltage under a 2 A pulse of 10 s duration.

such batteries begins with cell development and design. Qualification testing demonstrates the suitability of cells for implantable use. A careful and well-documented program of quality control is practiced throughout cell manufacture. Techniques for modeling cell performance must be developed so that device electronics and clinical procedures can adequately detect the approach of cell depletion in a timely fashion. A program of life testing is set up in order to verify accelerated test projections and spot any systematic defects or failures. This program has been demonstrated to be effective in producing high-quality, implantable-grade batteries for a variety of medical devices.

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