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Reliability systems for implantable cardiac defibrillator batteries

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Abstract

The reliability of the power sources used in implantable cardiac defibrillators is critical due to the life-saving nature of the device. Achieving a high reliability power source depends on several systems functioning together. Appropriate cell design is the first step in assuring a reliable product. Qualification of critical components and of the cells using those components is done prior to their designation as implantable grade. Product consistency is assured by control of manufacturing practices and verified by sampling plans using both accelerated and real-time testing. Results to date show that lithium/silver vanadium oxide cells used for implantable cardiac defibrillators have a calculated maximum random failure rate of 0.005% per test month.

Keywords: Implantable medical applications; Reliability

1. Introduction

Batteries for implantable medical applications must meet a specialized set of requirements. Particularly challenging are those demanded by the implantable cardiac defibrillator, a device implanted to detect and interrupt cardiac fibrillation. The device monitors heart function and, if deemed necessary, delivers a shock to the heart to interrupt fibrillation and allow the heart to recover to a normal beating rhythm. The monitoring function of the device requires cells to deliver currents in the microampere range for several years. The defibrillation function of the device requires batteries to rapidly deliver high current pulses to charge capacitors which supply the energy to defibrillate the heart. This set of performance requirements demands that cells have good low drain-rate characteristics and the ability to deliver ampere level current pulses with minimal voltage delay.

In addition to performance requirements, the reliability requirements for cardiac defibrillator batteries are significant since the defibrillator is a life-saving device. If a patient develops cardiac fibrillation with no intervention, it is likely the patient will not survive. Thus, in order for the cardiac defibrillator to function when required, the power source must work in a reliable and predictable way.

The systems that have been developed for the manufacture and control of implantable batteries are based on the Good Manufacturing Practices (GMP) guidelines developed for medical devices by the US Food and Drug Administration. The provisions of the GMP apply directly to medical device manufacturers, not component suppliers. However, the systems described here are in voluntary compliance with the GMP. Further, the documented systems meet the ISO 9001 requirements for design and manufacturing. This paper describes some of the methods used in developing and producing reliable cells for the implantable cardiac defibrillator as well as the reliability characteristics of cells that are being used for the application.

2. Cell design

One of the most critical aspects of providing a reliable power source is the cell design. The first step is to identify the chemical system for the product. The system should be chosen such that its characteristics are suitable for the application. For example, the cardiac defibrillator requires cells that must deliver high currents, have long life and provide end-of-service indication. For this application, the lithium/silver vanadium oxide (SVO) system was chosen. A solid cathode system was chosen to minimize effects of self-discharge under low drain rates and voltage delay under high pulse currents compared with lithium cells with liquid depolarizers. Also, SVO provides good rate capability and a sloping discharge curve that can aid in state-of-charge determination.

After the chemical system is identified, materials of construction must be chosen that are stable to the cell

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environment. For example, a glass seal that is resistant to corrosion is needed to ensure hermeticity over extended use. The TA-23 glass that was developed at Sandia National Laboratories is used for these cells. Other materials in the cell, such as the current collectors, must be compatible with the cell environment to minimize parasitic reactions.

The mechanical configuration of the cell must be developed to meet an additional set of requirements. The cells must have adequate surface area to deliver the current pulses demanded by the application, yet provide adequate safety and abuse resistance. The cell balance should be optimized to ensure that the energy density of the cell is maximized. Experimental design techniques are frequently employed in the optimization process. Redundant design features may be utilized in key areas to provide additional reliability of some critical features. Finally, the cells must be manufacturable.

The cell design used for the implantable cardiac defibrillator power source is shown in Fig. 1. The cell is prismatic with a multiplate cathode configuration. Cathodes are prepared by pressing SVO depolarizer on to metal grids. The cathodes and a strip anode are sealed in the separator. The anode is woven between the cathode plates which are then connected in parallel. The cell assembly is placed into a stainless-steel case, the terminal pin of the glass-to-metal seal is connected to the cathode leads, and the lid is welded to the case. The cells are vacuum filled with electrolyte and closed with a final weld to provide a hermetic package.

3. Qualification of components and cells

Once the design is proposed, work must be done to approve the design and the components. Key components undergo a qualification program. Typically, a series of tests is defined which determines the robust nature of the component and the suitability for use in the proposed design. For example, the lid and terminal assembly design is qualified to ensure that the assembly can withstand lid-to-case welding and other manufacturing processes without losing hermeticity at the glass-to-metal seal.

Even though many of the components in a cell may be qualified prior to use, the cell design itself is subjected to a qualification program prior to being released to production as an implantable-grade cell. The qualification procedure for the implantable defibrillator cells is shown schematically in Figs. 2 and 3.

Cells are tested under standard and abusive environmental conditions. For the standard tests the cells are tested fresh, half-depleted and fully depleted. Before and after each test the cells are examined visually, dimensionally, and by X-ray radiography to note the effects of the testing.

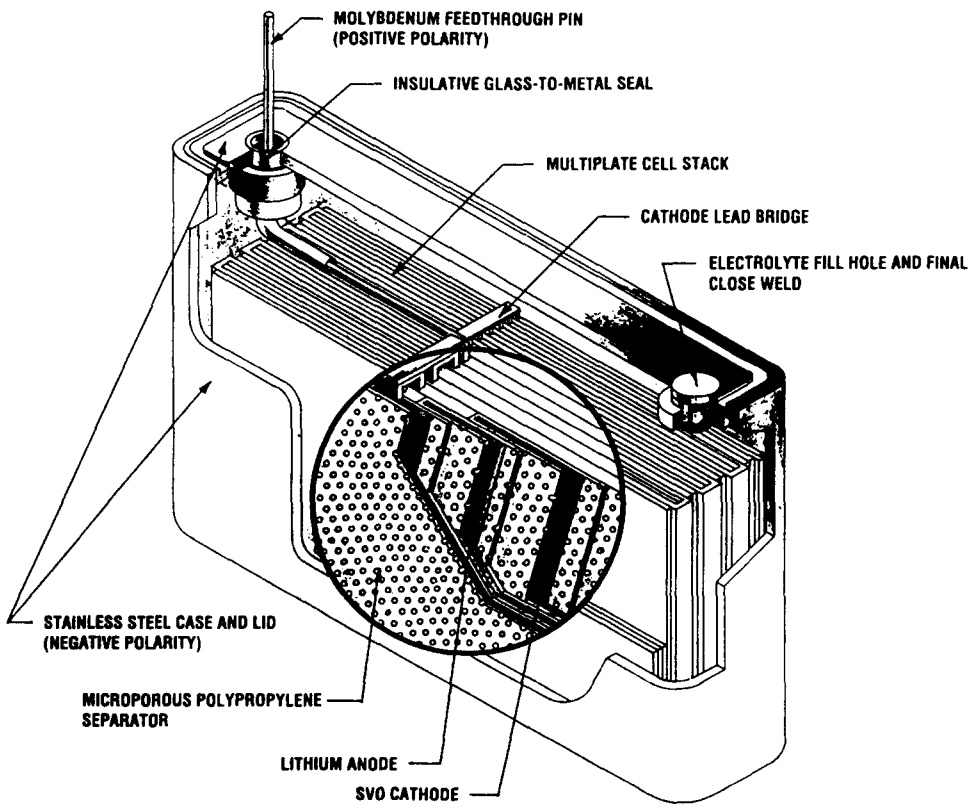

Fig. 1. Schematic of a lithium/silver vanadium oxide implantable cardiac defibrillator cell.

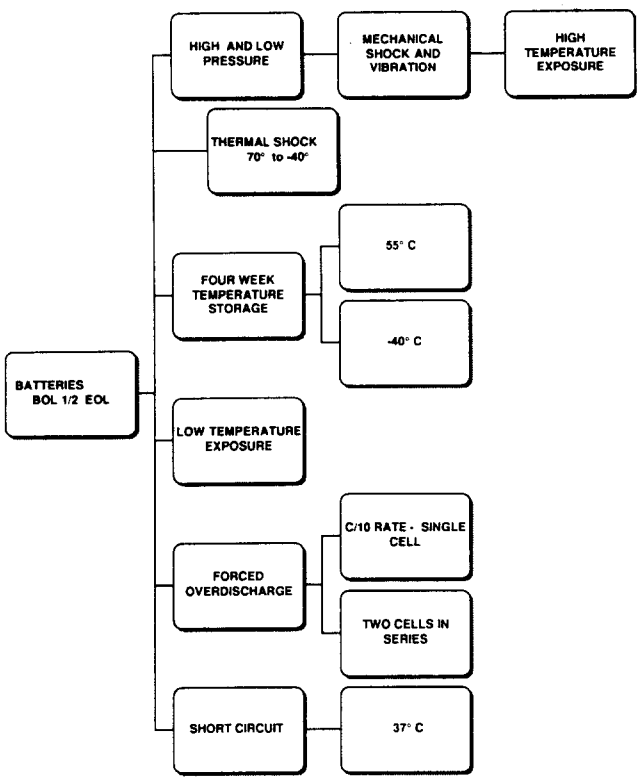

Fig. 2. Tests used as part of the qualification of implantable grade defibrillator cells. BOL = beginning of life, EOL = end of life.

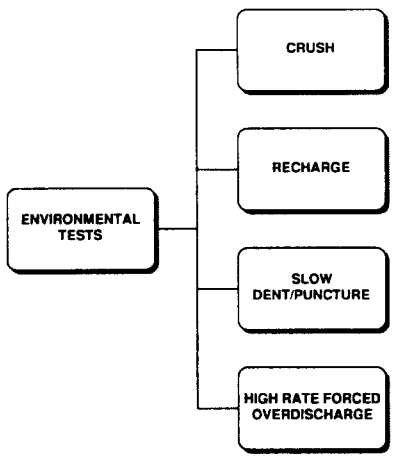

Fig. 3. Environmental tests conducted as part of the characterization of implantable grade defibrillator cells.

Abusive tests are conducted to determine the ability of cells to withstand the severe conditions imposed. While it is not a requirement for the cells to survive intact, the reaction of the cells to the conditions allows assessment of the hazards involved with such conditions.

Acceptance of the cell design also includes discharge testing to assess the ability of the cells to deliver the design capacity. Discharge testing may also be conducted on cells that have undergone several environmental tests such as exposure to high and low temperatures and pressures to determine the effect on cell performance.

At the completion of the qualification program the design is fixed. From that point on, the cell design can be changed only by use of the Engineering Change Order (ECO) system. This system requires that the change be documented, recorded, approved, and signed by designated representatives from seven functional areas. Significant changes are subjected to qualification schemes prior to acceptance and implementation. Every change must be supported by information justifying the modification.

A full-time auditor is maintained on the staff to support the quality system. Audits are conducted of production, inspection and documentation procedures on a regular, though random basis. A quantitative compliance index is calculated and reported.

4. Control of product consistency

One of the key steps involved in maintaining product control is ensuring that incoming materials remain in control. This is accomplished by vendor control programs, using only qualified vendors for critical components and a receiving inspection program. Vendors are subjected to inspection, documentation review and materials testing prior to use. Audits of vendor facilities are conducted as needed. Approved vendor lists are established for critical components based on the results of audits and testing. Incoming materials are sampled and tested according to predetermined plans. All parts that are received are assigned a lot number on arrival and a lot traveler which documents all operations performed on that lot. In order to allow traceability of all components and operations performed on the cell, each cell is assigned a unique serial number and tracked by a device history record. The lot travelers assigned to incoming materials become part of the device history record. These records are retained for a minimum of the expected device life.

During the production process, measurements and inspections are done on the cells and cell components to ensure that the defined criteria for each step are being met. Samples are taken at various steps to ensure that the production processes are in control. For example, samples are submitted for evaluation of welds to examine the metallurgical structure of the weld. Process and tooling setup is defined and controlled to maintain reproducibility of processes.

After the cells are complete, X-rays are recorded of each cell. Any anomalies are investigated and may result in the rejection of a cell. The cells are then subjected to electrical predischarge testing. A resistive load is applied to each SVO cell and used to remove about 1% of the cell's capacity. After 1 week of open-circuit

storage, one high current pulse train is applied. A pulse train consists of four pulses of 10 s duration where each pulse is followed by 15 s of rest. Data recorded during resistive discharge, open-circuit voltage, and during the first pulse train are examined to verify that the values are within the parameters established for the cell model. Prior to shipment, cells are subjected to a final leak test, visual inspection, and final verification of documentation.

5. Verification of product consistency

It is important to determine the product consistency and reliability over time. Therefore, several sampling and testing schemes have been devised to assess this characteristic. A sample of cells is continually taken from the production stream and subjected to accelerated discharge. Accelerated discharge testing is done by applying one pulse train, as described above, every 30 min. This testing scheme requires 2 to 3 days to fully deplete a cell. The results of this test on a cell with a capacity of 2.3 Ah are shown in Fig. 4. The data from these samples provide a rapid picture of any shift in the product performance.

Cells are also chosen quarterly and subjected to discharge at a 1 year rate to provide additional data on the consistency of the product. For example, a cell with a capacity of 2.3 Ah is loaded with a resistor of 17.5 kΩ, and one pulse train at an amplitude of 2.0 A is applied every 60 days. Results are shown in Fig. 5. Finally, 1 to 2% of cells built in production are tested at rates similar to or lower than those seen in field application. For defibrillator cells, half the cells are discharged under resistive load, generally 100 kΩ, and half are discharged under the resistive load with the application of one pulse train per month. An example of one of these tests is shown in Fig. 6. These tests are designed to simulate patient extremes where a patient is never defibrillated or the case where the patient is defibrillated once per month. Under 100 kΩ loads the largest cells may be on test for over 20 years.

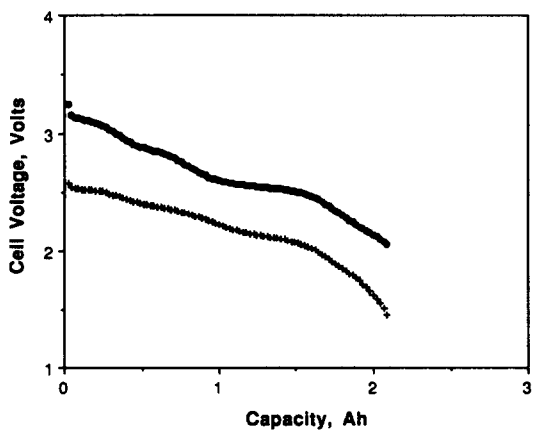

Fig. 4. Accelerated pulse discharge results of a lithium/silver vanadium oxide cell with a capacity of 2.3 Ah. The discharge scheme consisted of four 2.0 A pulses applied every 30 min where every pulse was 10 s in duration and was followed by 15 s of open-circuit rest. The prepulse voltage is indicated by the symbol (●) and the minimum voltage under the fourth pulse of each sequence in indicated by the symbol (+).

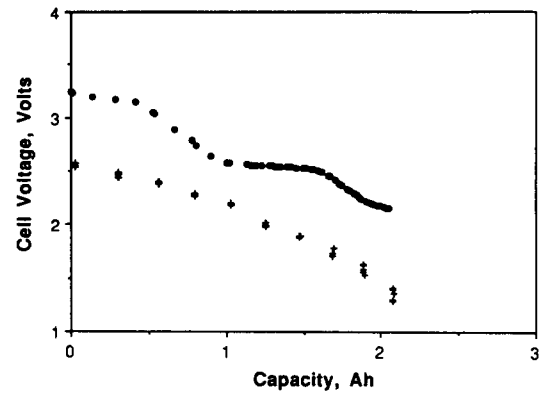

Fig. 5. Discharge results of a lithium/silver vanadium oxide cell with a capacity of 2.3 Ah. The discharge was accomplished by placing the cell under 17.4 kΩ background load and applying four 2.0 A pulses in a row every 60 days: (●) indicates the background voltage, while (+) indicates the minimum voltage of the fourth pulse of each pulse train.

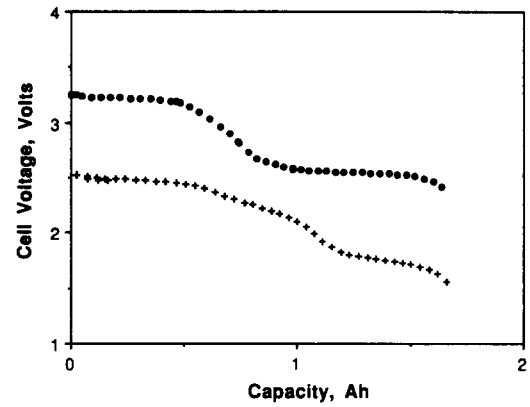

Fig. 6. Life test results of a lithium/silver vanadium oxide cell are shown. The cell was discharged under a 100 kΩ load with four 2.0 A pulses in a row applied every 30 days: (●) indicates the background voltage, while (+) indicates the minimum voltage under the fourth pulse of each pulse train.

6. Reliability results

Over 3800 Li/SVO defibrillator batteries are on life test under either a resistive load or monthly pulse scheme. No random test failures have occurred from this population where a failure is defined as an abrupt loss of cell function prior to reaching normal end of service. Based on over 46 000 cumulative test months, the calculated maximum random failure rate at 90% confidence for the cells either on resistive load or the monthly pulse scheme is 0.005% per test month.

7. Summary

Batteries for implantable medical applications present significant performance and reliability challenges. The implementation of a reliability program begins at the design stage and is carried through manufacturing. Verification of cell reliability is accomplished by a series of battery discharge tests, both accelerated and low rate. Currently, the population of cells on life test indicates a maximum calculated failure rate of 0.005% per test month.