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| 1a. <b>Unclassified</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |       | 1b. RESTRICTIVE MARKINGS <b>OTC FILE COPY</b>                                     |  |
| 2a. SECURITY CLASSIFICATION AUTHORITY <b>ELECTE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | 3. DISTRIBUTION/AVAILABILITY OF REPORT                                            |  |
| 2b. DECLASSIFICATION/DOWNGRADING SCHEDULE <b>SEP 08 1989</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |       | 4. PERFORMING ORGANIZATION REPORT NUMBER <b>ONR Technical Report 14</b>           |  |
| 5a. NAME OF PERFORMING ORGANIZATION<br><b>Dept. of Chem. Eng. &amp; Mat. Sci.<br/>Corrosion Research Center</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |       | 5b. OFFICE SYMBOL<br>(If applicable)                                              |  |
| 6a. ADDRESS (City, State, and ZIP Code)<br><b>University of Minnesota<br/>Minneapolis, MN 55455</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | 7a. NAME OF MONITORING ORGANIZATION<br><b>Office of Naval Research</b>            |  |
| 8a. NAME OF FUNDING/SPONSORING ORGANIZATION<br><b>DARPA/ONR</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |       | 8b. OFFICE SYMBOL<br>(If applicable)<br><b>Code 1113</b>                          |  |
| 9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER<br><b>Contract No. N00014-88-K-0360</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |       | 10. SOURCE OF FUNDING NUMBERS                                                     |  |
| 11. TITLE (Include Security Classification)<br><b>The Use of Lithium Batteries in Biomedical Devices</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |       | 12. PERSONAL AUTHOR(S)<br><b>Boone B. Owens and P.S.S. Prasad</b>                 |  |
| 13a. TYPE OF REPORT<br><b>Technical</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |       | 13b. TIME COVERED<br>FROM <b>7/88</b> TO <b>6/89</b>                              |  |
| 14. DATE OF REPORT (Year, Month, Day)<br><b>89/06/15</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |       | 15. PAGE COUNT<br><b>10</b>                                                       |  |
| 16. SUPPLEMENTARY NOTATION<br><b>The Electrochemical Society of Japan, 9/25/89,<br/>proceedings of the Ninth Discussion Meeting of New Battery Conceptive Division</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |       |                                                                                   |  |
| 17. COSATI CODES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |       | 18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number) |  |
| FIELD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | GROUP | SUB-GROUP                                                                         |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |       | lithium; batteries; biomedical devices; (KT)                                      |  |
| 19. ABSTRACT (Continue on reverse if necessary and identify by block number)<br><p>The market for lithium batteries has been growing steadily during the past fifteen years as these new types of power sources have been developed into reliable sources of power. Primary lithium batteries have been used in military, commercial and biomedical applications for over ten years and they have proven to be an increasingly important class within the battery industry. Rechargeable lithium batteries are the subject of considerable development activity, with some small cells having been already commercialized. However, the implementation of rechargeable lithium batteries on a wide spread basis still awaits the further development and qualification of new designs.</p> |       |                                                                                   |  |
| 20. DISTRIBUTION/AVAILABILITY OF ABSTRACT<br><input checked="" type="checkbox"/> UNCLASSIFIED/UNLIMITED <input type="checkbox"/> SAME AS RPT. <input type="checkbox"/> OTC USES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |       | 21. ABSTRACT SECURITY CLASSIFICATION<br><b>Unclassified</b>                       |  |
| 22a. NAME OF RESPONSIBLE INDIVIDUAL<br><b>Boone B. Owens</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |       | 22b. TELEPHONE (Include Area Code)<br><b>(612) 625-1332</b>                       |  |
| 22c. OFFICE SYMBOL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       |                                                                                   |  |

**NINTH DISCUSSION MEETING OF NEW BATTERY CONCEPTIVE DIVISION**  
**Electrochemical Society of Japan**  
**Kyoto University**  
**Kyoto, Japan**  
**9/25/89**

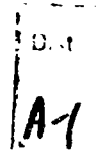
**THE USE OF LITHIUM BATTERIES IN BIOMEDICAL DEVICES**

**Boone B. Owens and P. S. S. Prasad**  
**Corrosion Research Center**  
**Department of Chem. Eng. and Mat. Science**  
**University of Minnesota**  
**Minneapolis, MN-55455, U.S.A.**

The market for lithium batteries has been growing steadily during the past fifteen years as these new types of power sources have been developed into reliable sources of power. Primary lithium batteries have been used in military, commercial and biomedical applications for over ten years and they have proven to be an increasingly important class within the battery industry. Rechargeable lithium batteries are the subject of considerable development activity, with some small cells having been already commercialized. However, the implementation of rechargeable lithium batteries on a wide spread basis still awaits the further development and qualification of new designs.

One of the first uses of a lithium primary battery was the implant of a lithium powered pacemaker in Ferrara, Italy, in March of 1972. Since that time lithium batteries have effectively replaced aqueous electrolyte batteries from the market for cardiac pacemakers and well over three million lithium batteries have been implanted in humans as the power source for cardiac pacemakers. Real time testing of lithium cells has gone out to as much as sixteen years and they have acquired an excellent record of reliability for this very critical application.

The subject of implantable power sources has been the topic of several recent review articles; for example Owens (1986), Holmes (1987), Owens and Munshi (1988) and Holmes (1988).



For many years, passive artificial prostheses have been implanted into the human body to treat a variety of disorders. However, electrically powered implantable devices were not utilized prior to 1960 because of the relatively large volume and power requirements for the systems. With the advancement of electronic components and miniaturization of electronic circuitry, small implantable devices started to become practical and it was after the 1960s that high energy density batteries were used in implantable devices. Although the cardiac pacemaker is the major implantable battery powered device in use, a large number of other has also been implanted and/or developed. Some of these are summarized in Table 1 (Owens and Munshi 1988).

TABLE 1. IMPLANTABLE DEVICES IN CLINICAL PRACTICE OR DEVELOPMENT

|                             |                          |
|-----------------------------|--------------------------|
| (1) artificial larynx       | (8) gut stimulator       |
| (2) artificial heart        | (9) hearing aid          |
| (3) artificial vision       | (10) heart assist device |
| (4) automatic defibrillator | (11) heart pacemaker     |
| (5) bone growth stimulator  | (12) implantable sensor  |
| (6) drug infusion system    | (13) neurostimulator     |
| (7) gait assist device      | (14) pain suppressor     |

The preferred power source for pacemakers remains the



battery system, where PVP represents poly-2-vinylpyridine.

This solid state battery is not applicable to other higher power applications. The lithium iodide electrolyte has a high resistance which limits the power capability of this system to several microwatts per square centimeter electrode area. The cell initially has an extremely thin electrolyte layer formed in-situ at the time of initial cell assembly, according to the reaction



The net electrochemical discharge reaction is the same and produces additional electrolyte which increases the internal resistance of the battery .

Certain design features have been described in the literature (Owens 1986) and the resistance can be minimized to some extent. However, the system is still restricted to very low power levels. This has not been a significant hindrance to its application in pacemakers where the circuitry requires about 40-100 microwatts. The ability of this lithium/iodine battery to deliver such small power levels for time periods in excess of ten years, with very little self-discharge and excellent reliability has been critical in the development of modern implantable pacemakers. These pacing devices which at one time were relatively bulky and heavy in size now are as light as 25 grams. Thus, although the lithium/iodine battery was instrumental in the pacemaker industry, most of the devices listed in Table 1 cannot be operated with such low power densities.

The power requirements for implantable devices vary from about 25 microwatts for a bradycardia pacemaker up to a continuous power requirement of greater than ten watts for a totally artificial heart. An assessment of electrochemical power sources for all these applications must therefore consider all types of batteries ranging from very low rate up to very high rate, high energy density designs. The general requirements for an implantable battery are shown in Table 2.

TABLE 2. BATTERY PERFORMANCE GOALS FOR IMPLANTABLE DEVICE POWER SOURCES

- 
1. Optimized performance at 37°C
  2. Safety
  3. High reliability
  4. Longevity
  5. Small size -- high energy density
  6. Small mass -- low specific gravity
  7. Predictable discharge behavior
    - (a) Gradual loss of power (no abrupt loss of output)
    - (b) State of discharge indicator
    - (c) Intrinsic end-of-life indicator (adequate replacement time interval)
-

The types of implantable batteries that have been developed may be categorized with respect to their power capabilities, as shown in Table 3 (Owens and Munshi 1988).

TABLE 3. CLASSIFICATION OF IMPLANTABLE DEVICES BY POWER LEVEL

- 
1. **Low-current - microampere range**
    - (a) heart pacemaker
    - (b) bone growth stimulator
  2. **Medium-current - milliampere range**
    - (a) implantable drug delivery device
    - (b) implantable neurostimulator
  3. **High-current - ampere range**
    - (a) automatic implantable defibrillator
    - (b) ventricular assist device
- 

The cardiac pacemaker is the most well known example of a low power, low-current implantable device, typically operating at about 10-50 microamperes with a nominal load voltage of 2.5 volts. The medium-current devices require average currents or pulse currents in the milliampere range and are exemplified by implantable drug delivery devices in which the battery powers both the microelectronic control system (at a very low level of current) and a pumping system that operates intermittently on a preprogrammed schedule. The high-power devices require currents in the ampere level, which may be an intermittent pulse current as in the case of an implantable defibrillator, or an average current as in the case of a ventricular assist device.

In the last twenty years the size of the battery in cardiac pacemakers has been reduced from as many as ten one ampere-hour mercury/zinc cells down to a single sub ampere-hour lithium/iodine cell of 4 millimeter thickness. This reduction in size has happened while the operating lifetime has been increased from one and half years up to as much as ten years. Since the first implant of a lithium/iodine battery-powered pacemaker in 1972, eight different lithium battery systems have been used in devices that were implanted in humans. Table 4 illustrates the different systems that have been evaluated in implantable applications. (Holmes 1989 , Owens 1986).

TABLE 4. LITHIUM BATTERY SYSTEMS USED IN IMPLANTABLE DEVICES

- 
- (1) Li / LiI / I<sub>2</sub> (PVP)
  - (2) Li / LiClO<sub>4</sub>, PC / Ag<sub>2</sub>CrO<sub>4</sub>
  - (3) Li / LiClO<sub>4</sub>, DOL, DME, DMI / CuS
  - (4) Li / LiAlCl<sub>4</sub>, SOCl<sub>2</sub> / SOCl<sub>2</sub>
  - (5) Li / LiI (Al<sub>2</sub>O<sub>3</sub>) / PbI<sub>2</sub>, PbS, Pb
  - (6) Li / LiBr / Br<sub>2</sub>, PVP
  - (7) Li / LiAlCl<sub>4</sub>, SOCl<sub>2</sub>, BrCl / SOCl<sub>2</sub>, BrCl
  - (8) Li / LiClO<sub>4</sub>, PC / MnO<sub>2</sub>
- 

\* PC = propylene carbonate, DOL = 1,3-dioxolane, DME = 1,2 dimethoxy ethane, DMI = 3,5-dimethylisoxazole.

The typical cardiac pacemaker battery specifications are shown in Table 5 (Owens and Munshi 1988). The first six cell systems shown in Table 4 were clinically evaluated in cardiac pacemakers. Today only the lithium/iodine system is used to any extent in this application.

TABLE 5. TYPICAL CARDIAC PACEMAKER BATTERY SPECIFICATIONS

---

| Property           | Value            |
|--------------------|------------------|
| Output voltage     | 2.5 volts        |
| Current drain      | 10-30 microamps  |
| Operating lifetime | 5-10 years       |
| Capacity           | 1-3 ampere hours |
| Thickness          | 5-8 millimeters  |
| Volume             | 5-10 milliliters |
| Weight             | 10-25 grams      |

---

In describing the power requirements, it is important to distinguish between the average background or monitoring current required for many of these devices and the peak power requirement that may be required on a continual basis or only intermittently on demand. Table 6 gives the typical values for implantable devices in the order of decreasing power requirements (Owens and Munshi 1988).

TABLE 6. CURRENT REQUIREMENTS OF IMPLANTED DEVICE BATTERIES

| Device                   | Average Current<br>(microamperes) | Pulse Current<br>(milliamperes) |
|--------------------------|-----------------------------------|---------------------------------|
| artificial heart         | 1000000                           | 1000-2000                       |
| defibrillator            | 10-80                             | 2000                            |
| neurostimulator          | 10-20                             | 1-5                             |
| drug pump                | 20-50                             | 1-2                             |
| tachyarrhythmia control  | 20-100                            | 2                               |
| dual chamber pacemaker   | 20-100                            | -                               |
| single chamber pacemaker | 10-100                            | -                               |

The lithium/iodine system has demonstrated excellent reliability as previously stated. Holmes (1987) reported real time test results that had run continuously at 37°C for 160 months as shown in Figure 1.

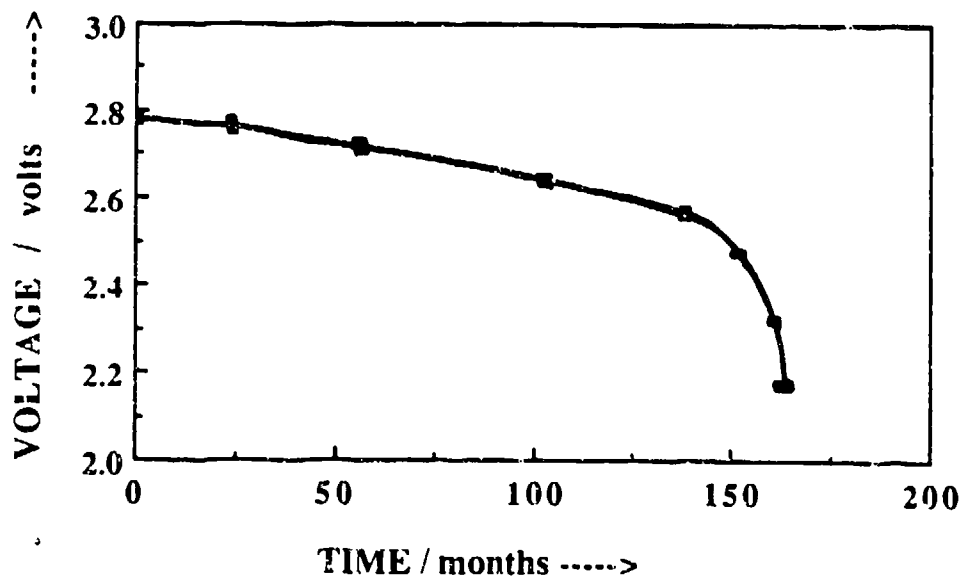
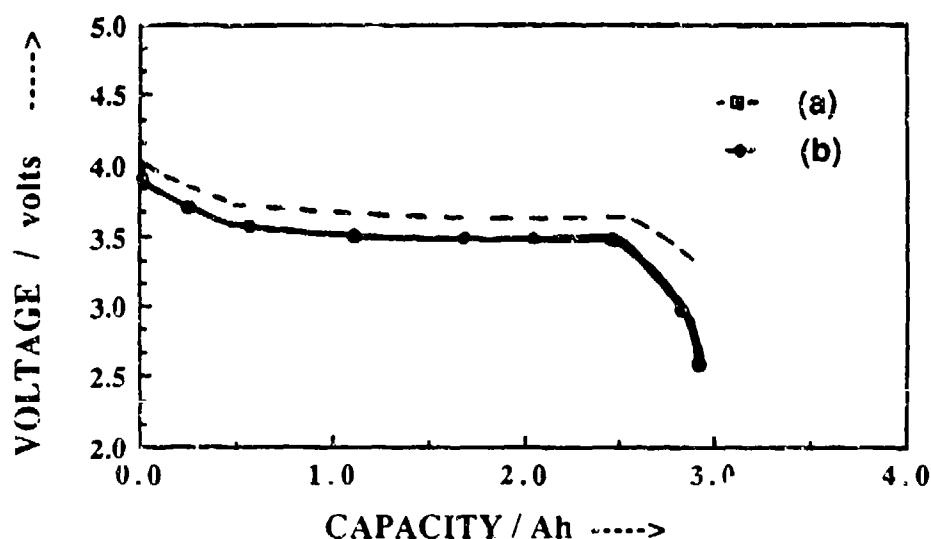


FIGURE 1 : Discharge curve of Li/I<sub>2</sub> system under 100 KΩ load for 160 months at 37 °C

## Medium-Current Battery Applications

The medium current applications require average currents in the order of 20 microamperes, but with the ability to deliver pulse currents from 200 microamperes up to several milliamperes. This power requirement has been provided by both the lithium/thionylchloride battery and the lithium/BCX battery (BCX is the Wilson Greatbatch Ltds designation for the soluble cathode battery in which the liquid depolarizer is a mixture of thionylchloride with bromine chloride). The results obtained at Wilson Greatbatch Limited on their tests of the Li/BCX battery are shown in Figure 2 (Holmes 1987).



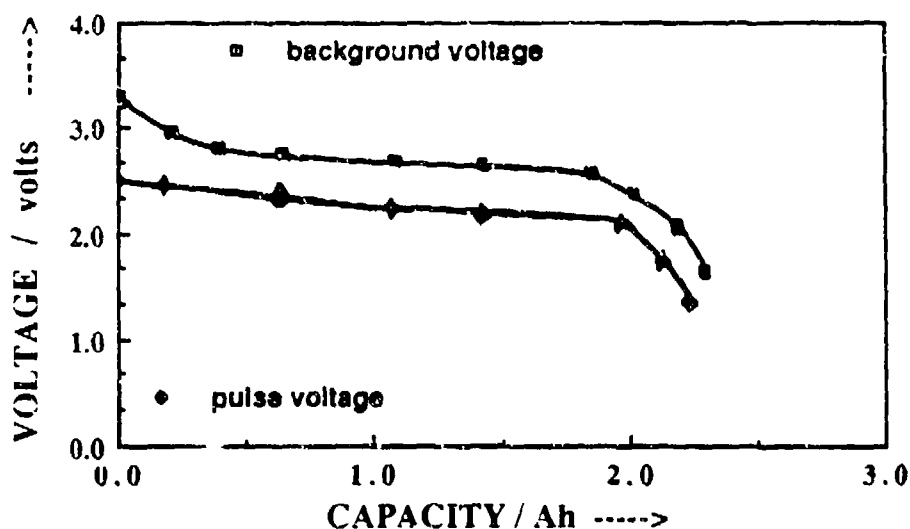
**FIGURE 2 : Discharge curve of Li/BCX battery**  
(a) cell voltage under 30 mA background current  
(b) voltage under a pulse train of 1.3 mA and duration of 10 seconds, which was imposed every 2.4 minutes over the background current

Although initially the lithium liquid depolarizer batteries appeared to have excessive self-discharge, design improvements and further analysis of the performance characteristics of these batteries have resulted in predictable performance for the conditions of these low drain applications with intermittent pulse currents.



## High-Current Drain Devices

The high-current devices are exemplified by the automatic implantable defibrillator that operates at a low monitoring current, on the order of 10 microamperes for a period of several years. At some unknown time during this interval, if the patient's heart suffers a fibrillation, this is detected by the sense circuit and the battery is then required to charge a capacitor up to several hundred volts in a matter of about 10 seconds. The capacitor is then discharged across the heart to terminate the fibrillation. The battery current drain can approach 2 amperes during the charging time. If the fibrillation is not broken, this pulse sequence is repeated up to about four times. Multiplate low internal resistance designs of the lithium/nonaqueous electrolyte/vanadium pentoxide and silver vanadium oxide batteries have been designed for the defibrillators. The voltage-capacity performance of the lithium/silver vanadium oxide defibrillator battery under pulse-test conditions at 37 °C is shown in Figure 3.



**FIGURE 3 : The voltage-capacity performance of the lithium/silver vanadium oxide defibrillator battery under pulse-test conditions at 37 °C**

These prismatic cells have been shown to function reliably in this application; however, the implantable defibrillator is a large device, with present models weighing about 250 grams, occupying a volume of 150 cc and having dimensions of nearly 11 cm x 8 cm x 2 cm . The major part of the internal volume of the device is occupied by the capacitors and the batteries. As implantable defibrillator technology advances and clinical usage increases, it will be necessary to reduce the size. The success in achieving this will in part depend upon new developments in high energy power sources.

The highest power requirement is for the ventricular assist device or the total artificial heart. In this case the average current drain on the battery is about 1 ampere for a 12 volt battery pack. Clearly this cannot be met with a primary battery as any reasonable size would have an operating time of less than 24 hours. If an implantable system is to be developed for this requirement, then rechargeable power sources will have to be relied upon. Small rechargeable batteries are designed into such systems as back up power supplies for designs wherein the primary power supply is external to the body and the energy is transmitted by electromagnetic induction through the skin to a receiving coil.

### Conclusions

Biomedical implantable devices have benefited greatly from developments in the battery field. The availability of high energy, hermetically sealed, long life lithium batteries has played a major role in this field and has been crucial to modern day pacemakers. The need for higher power levels in the future may be met as safe rechargeable lithium batteries are evolved. In summary, there will be continuing use of primary lithium batteries in this field and rechargeable systems will also prove to be of significant use.

### Acknowledgement

The authors wish to acknowledge the financial support of the Office of Naval Research (ONR) and the Defense Advanced Research Projects Agency (DARPA).

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