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BATTERY GUIDELINES (DRAFT)

By Albert E. Moyal

The various types of batteries that are used throughout in everyday life are, in essence, transducer devices that convert chemical reactions. These reactions characterize the battery type and performance. There are two styles of batteries that are available: primary and secondary batteries.

The primary batteries are batteries that can only be used once. They can provide the highest energy density possible (3 to 10 times the energy density of typical rechargeable batteries), minimal maintenance, low self-discharge and availability in a wide range of shapes and sizes. The Carbon-Zinc, Alkaline, Mercury, Silver, Zinc-Air and Lithium, are examples of such batteries. The big disadvantage, though, of using such batteries, is the one time use. This makes them economically not practical in applications where there is a high current demand.

Secondary Batteries are batteries that can be repeatedly recharged. They provide the user with convenience and economic advantages. In comparison to primary batteries, rechargeable batteries have applications that are more complex and require careful selection and design considerations. Considerations such as run-time before rechargeability (a critical competitive factor) and higher battery capacity with lower device power consumption, can mean more hours of operation prior to bringing the device (or battery) for recharging.

THE RECHARGEABLE BATTERY

There are several types of rechargeable batteries that have been introduced and marketed. The Lead-Acid Battery was designed for shallow discharges and high amperes ideal for the automotive industry. These batteries were not utilized within the medical field due to the intolerance of frequent discharging and fast charging needed. In addition, the potential leakage of sulfuric acid fumes during to extreme current drain conditions, made them very unattractive for medical uses.
Recent advances have allowed the use of Lead-Acid Batteries in portable X-ray machines.

The Nickel Metal-Hydride battery is a new technology being worked on that can provide a 50% increase in energy density compared to Nickel Cadmium batteries. The Lithium battery has been recently introduced with energy densities of greater than twice that of

Ni-Cad batteries.

The Nickel-Cadmium battery is the most widely used rechargeable battery. Its efficient charge and discharge characteristics, reliability and economic nature have made it very popular and widely utilized in the medical industry.

The performance and life-span of a rechargeable battery depends on several factors. Battery operating conditions of temperature, current drain, and charge/discharge method, are taken into account in the design of such batteries.

The goal is to develop a battery that maintains its battery capacity as high as possible and as long as possible. Manufacturers have developed nickel-cadmium batteries that can be charged up completely in one hour. A recent development by Panasonic Industrial is the use of a sponge-metal electrode that can increase the volumetric density by 35% compared to the sintered-metal electrode that are used in standard versions.

FDA CONCERN

This is a list of the areas of concern with regards to rechargeable batteries (battery packs are included within this designation). The recommended information should be requested of the manufacturer's of Batteries, that are to be used with various medical devices, in order to help verify their integrity and performance.

Much of the information needed is usually accomplished by the manufacturer of the battery cells, and not the distributors or modification centers.

1. Labeling of the battery pack.

    Which medical devices will the batteries be used with.

2. Comparison with Predicate Device Battery pack (or cell).

    Complete detailed description and comparison of similarities and differences between the battery in question with a predicate (or OEM) battery.

    Include comparison(chart or table) between the two batteries of: intended use (voltage supply), size specifications, Battery type, capacity (in amp hours), casing, connection method, recharge capability, and venting of battery.

3. Life Cycling Testing of the battery pack (or cells).

How many recharge & discharge cycles will the battery packs (and the individual battery cells used within the packs) be effective for? 100?, 500? This amount must be provided.

4. Temperature Testing of the battery pack (or cells).

Show the Temperature ranges the battery packs (or cells) were tested in and can operate safely in, as in the following:

- Available Capacity (%) vs. Operating Temperature

5. Discharge Aspects of the battery cells w/in the battery pack.

Graphs that show the following information are needed:

A. Available Capacity (%) vs. the Discharge Rate (C)

B. Cell Voltage (V) vs. Discharge Time (hrs) (at low rate)

C. Cell Voltage (V) vs. Discharge Time (hrs) (at high rate)

D. Cell Voltage (V) (Operating Voltage) vs. Discharge Rate (C) (at various discharge states)

This is usually done and provided by the manufacturer of the battery cells (not the distributor).

6. Qualification Testing of BOTH the battery cell and battery packs.

This includes the Protocol, Pass/Fail Criteria, and Results of Testing done on the battery packs and battery cells.

Regarding the finished battery packs, this is the verification and screening, of final Voltage and Amp-Hours of the combined batteries within the battery pack.

*7. Functional Testing of the battery packs.

Complete functional testing is required of the battery pack with the devices they will be used, in two situations:

A) If the medical device the battery will be used with is a Class III Device (i.e. Automatic and Semi-Automatic External Defibrillators, Defibrillators with Pacing Option).

B) When a submission is seeking approval for one or two battery packs to be used with a certain device, or devices.

In this instance, a manufacturer of a device wishes to market a rechargeable battery to be used with their device, and perhaps, several others (ie, company A wishes to market a battery to be used with their device and/or company B's device). This is when functional testing should be done.

8. Maintenance Protocol to be provided to the End User of the battery pack.

This is to ensure optimal performance by the end user of the battery. Some type of outline must be provided, by the applicant, to the end user, to ensure that the batteries used are maintained properly to ensure the longevity of the battery and proper use of the device.

This outline should detail the specifics of charging i.e. when to charge and when not to charge, how to charge (if high speed charging is used). Some batteries need to be totally discharged before recharging is accomplished, ie, do not charge the battery if it has not used up all its capacity.

Question may be worded in the following manner: Please incorporate within the labeling of the batteries provided to the end users, some type of outline for the maintenance of the batteries. Please state any discharge/recharge requirements that the batteries may have.