Design of Medical Devices: Batteries Designed to Accommodate Sterilization

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Many medical devices, such as those used in surgery, must be sterilized prior to use. The operating table is surrounded by a sterile zone; untethering surgical devices increases the ease of maintaining and simplifying the sterile area, but battery packs, especially rechargeable battery packs, present unique challenges for sterilization. There are three strategies for sterilizing devices. The compatibility of each with battery technology varies for both chemistry and pack design, but solutions have been implemented or proposed for powering surgical devices with a battery, regardless of the sterilization method required.

Battery options:

There are a few common chemistry options for non-rechargeable, or primary, batteries. Alkaline batteries are very common, but the voltage is low so many products are designed to be used with Li-primary batteries. Cameras are probably the best known example, but some medical products also rely on Li-primary batteries for power. Automatic External Defibrillators (AEDs) are becoming ubiquitous, and they are enabled by the long, more than five year, shelf life of the Li-primary batteries.

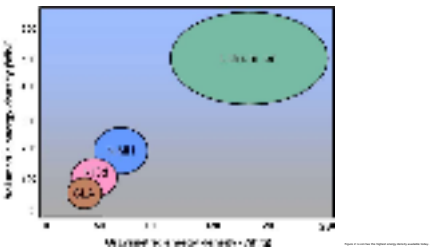
Figure 1: This NiMH battery pack is specially designed to survive sterilization in an autoclave

There are three rechargeable battery options for portable devices; all of them are common in the consumer and medical world. Each rechargeable battery chemistry has applications for which it is well suited. Nickel Cadmium batteries have the lowest energy density of the options and are plagued by the memory effect, but their rate capability is superb, so they are used in cordless power tools, both those used in construction and orthopedic surgeries. Nickel Metal Hydride (NiMH) cells demonstrate a great improvement in energy density over NiCd, but self-discharge rates are about 30% per month.
Lithium Ion (Li-ion) technology was introduced commercially in 1991, and with it’s operating voltage that is 3 times that of NiMH, Li-ion’s energy density is the best available today, as shown in figure 1. It is the chemistry of choice for handheld devices. Li-ion cells operate effectively between -20° and +60° C. Of all the chemistries listed above, Li-ion requires the greatest degree of protection, including a thermal shut down separator and exhaust vents (within each cell) to vent internal

pressure, an external safety circuit that prevents over-voltage during charge and under-voltage during discharge, and a thermal sensor that prevents thermal runaway. However, with the appropriate level of safety designed into a Li-ion pack, Li-ion offers the most attractive cell chemistry even when exposed to the extremes temperature and chemical environments imposed by sterilization procedures.

The Sterilization Options:

The most common sterilization method available in a hospital or clinical setting is the autoclave. In fact, autoclaves are even used in dentist offices and it is the most often used method for surgical tools such as the handheld orthopedic tools mentioned above. The autoclave uses a combination of high temperature and pressure to sterilize equipment. Autoclaved batteries are exposed to temperature extremes far beyond the cell manufacturer’s recommendation. The tools and battery packs must withstand temperatures up to 137° C and are impermeable to 30 psi of superheated steam and they must have a battery that allows the surgeon enough run time and power to complete major orthopedic procedures. Figure 2 shows a surgical tool battery pack that is specially designed to survive the extreme conditions of an autoclave with minimal deterioration in performance. For this application NiMH cells are used. The plastic housing is a glass blend that will help it to withstand the heat and the pieces are sealed together with a gasket and screws. A valve allows the pack to vent. Throughout the pack the materials selected must withstand the elevated temperatures, so even the interior glue and thermistor must be specified for high temperature use. Designs like this allow medical battery packs to be used in sterile surgical environments bringing ease of use and efficiency.



Extremely high temperature operation provides even more challenge for cells based on lithium chemistry. As mentioned earlier, the upper range of safe operation for Li-ion cells is 60° C. Cells provide energy through the electrochemical shuttling of lithium ions between the anode and the cathode materials. However, at high discharge rates this chemical reaction generates heat, and so high drain rate applications must be designed with extra caution. The affects of the generated heat is compounded when numerous cells are assembled into a multi-cell pack. Some new chemistries, however, have been introduced that are less reactive at high temperature. These new chemistries have the additional benefit of an improvement in rate capability. The new chemistries have cathodes based on iron phosphate, manganese spinel or a solid solution of Nickel, Cobalt and Manganese oxide. While these cells are less likely to cause explosion or fire if placed in an autoclave, they share the feature of a polymer separator with their predecessors. The polymer separator will certainly melt at high temperature, rendering the

battery inoperable, so the sterilization process would need to use aseptic transfer, a process whereby the core pack of the battery is removed prior to the sterilization of the exterior case. Ethylene Tri-oxide Gas (ETO) is sometimes used as an alternative to autoclaving. While this process provides promise that Li-ion chemistries can be more easily sterilized, there are complaints that ETO does not always have good penetration, and the battery would need to be tightly sealed because of corrosion because any gas that enters the pack will cause corrosion of the circuit board. Corrosion of the contacts is another obvious problem.
Gamma radiation is sometimes used for disposable medical equipment since it is performed at the medical OEM's site rather than at the hospital. Of course, it makes sense to use Li-primary batteries in one time use equipment. Manganese dioxide based cells should be used since they are not pressurized. Also, care should be taken that the cell's separator is a straight chain olefin, such as poly propylene, and even these polymers can be embrittled by a very high dose of radiation.

Sterilization adds complexity to battery design. Understanding the usage profile of a battery for a medical device is the most important step in designing a battery that will perform reliably, and when it is necessary to expose the battery to the extreme environment presented by sterilization the use model must be very exact for the battery to be designed to perform as expected.

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