



Increasingly, medical-device OEMs work with battery designers on custom battery packs designed specifically for an application rather than accepting the compromises inherent with off-the-shelf batteries. Customized batteries meet size, weight, and performance needs, and can include safety features, and tailored functions such as runtime indicators, authentication functions, and data logging, if the user chooses.

Consider several factors when designing battery-powered devices. These include safety, battery life, safe and efficient charging, accuracy of the run-time gauge (fuel), impact of high-temperature sterilization, and complying with regulations.



**Batteries for portable devices come in wide array of sizes and shapes. Battery chemistries alone total at least a dozen.**

### **Safety**

Safety is a primary concern. Any battery contacting a patient must not present a shock hazard, create unwanted heat, or react with materials already in the patient's body or surroundings. Ports that might be accessed by users or patients must be protected against short circuits, electrostatic discharge, and other electromagnetic interference.

Lithium-ion (Li-ion) is the battery chemistry of choice for today's portable medical equipment because of its high energy density. However, that comes with a price: an increased need for safety measures. Hence, several safety mechanisms are built into Li-ion battery packs. These may include a thermal-shutdown separator, pressure-activated current interrupter, pressure vent, over-current protection, and a thermal fuse built into the cell. Additional protection in the battery pack includes an electronic safety circuit, which protects the cells from excessive voltage or current, and over discharge. Protection is also provided by over current and high-temperature fuses.

Further safety considerations include designing batteries in which safety vents are unobstructed and the cells are separate from heat-generating components in the battery management circuit. Putting batteries in host equipment away from an internal heat source also adds a level of safety and prolongs the life of the battery.

### **Battery life**

With every use, a battery's recoverable capacity decreases slightly depending on the depth of the discharge. As the battery cycles, it can no longer deliver 100% of its rated capacity. For example, on its 100th charging cycle, a battery that registers fully charged would likely hold only 90 to 95% of the charge it held when new. Hence, users should expect somewhat less than the battery's original capacity for most of the pack's usable life. A battery is generally considered near the end of its life when fully charged is really only equal to 80% of its capacity when new. For most batteries, that cycle life is between 300 and 500 full cycles.

Designers can manipulate several parameters to increase battery life. For example, reducing the charge voltage extends cycle life with only a small penalty in capacity. If cycle life is critical, reducing the charge voltage on Li-ion rechargeable batteries to 4.1V/ cell instead of the typical 4.2V increases cycle life by as much as 30% while reducing capacity only 10%.

### **Balanced charging**

Li-ion batteries are generally charged using a regulated voltage with limited current. In the early portion of the charge cycle, current is constant and voltage rises to its regulated value. After reaching it, current gradually decreases as the battery reaches full capacity. Generally, charging ends when the current falls below a predetermined level.

It is important that all cells in a multicell pack remain balanced with respect to capacity and state of charge. That's because charge is limited by the cell most full, while discharge is limited by the cell least full. In other words, one cell's state-of-charge limits the performance of the entire battery pack. Manufacturers must grade and match cells according to capacity, state-of-charge, and impedance, especially for Li-ion packs. Cell age, temperature, and use (or abuse) all influence this voltage balance.

Cell balancing during charge and discharge gets the most from a pack. There are two primary ways to balance cells. Resistive cell balancing reduces the charge to the cell with the highest state of charge by shunting charge around it until the remaining cells catch up. Cell balancing by charge transfer uses circuitry to move charge from one cell to another. This can actually raise the effective capacity of a battery pack beyond that of its weakest cell. However, it is more complex and costly than resistive cell balancing.

But be careful not to overuse cell balancing. A significantly out-of-balance cell might be a sign of an internal problem, and that might present a safety hazard if the laggard cell is continually forced into balance with others.

A fuel gauge is more than a fringe benefit on battery packs in medical devices. The fuel gauge is an advanced warning system for low-charge or situations that signal the end of the device's batteries.

Previous battery state-of-charge indicators have not been reliable. An EMT would be unconcerned responding to an accident five miles away in an ambulance with a half tank of gas. A doctor, however, would not think of beginning even simple procedures with a portable monitor registering a half-full battery.

An accurate state-of-charge indicator has been difficult to build because it was difficult to accurately determine a battery's state-of-charge while it is in use. Predicting a battery's remaining run-time has improved significantly over the past few years thanks to advances in the microprocessing capability of battery electronics that tracks several variables. Also, more advanced methods let fuel gauges relearn the capacity without having to do full cycles. These make it possible to get readings that are accurate to within 1%.

To remain accurate, the battery pack's fuel gauge must relearn the actual full-charge capacity due to the loss in capacity with age and stress, and adjust that calculation for the existing present discharge rate and temperature. Relearning capacity was previously done by fully discharging the pack so it could measure its capacity. However, this requires fully charging the battery and discharging it to nearly empty. In the hustle of medical care environments, relearning is not regularly scheduled or practical in most cases. It must be done off-line with controlled charge and discharge cycles. Relearning is often ignored and users incorrectly assume the displayed capacity is still valid.

Fuel gauges track capacity by integrating the current flow in and out of the battery over time (by counting coulombs or milliamp hours). Using voltage alone for the task is long outdated and insufficient. Some new fuel gauges combine coulomb-counting with measurements of the state-of-charge while in relaxation mode (no activity and stable voltages). This provides accurate fuel gauge readings and lets packs relearn

### Recent advances

Emerging variations of Li-ion chemistry are expanding the range of charge and discharge voltages beyond that of batteries used in most of today's medical devices. A few of these technologies offer higher capacity, longer cycle life, faster charge rates, lower impedance, and most significantly, higher levels of safety. Rapid adoption of these new chemistries will be possible through use of fuel gauges that include protection with programmable thresholds, however, compatibility issues must be addressed for legacy charging systems already deployed. Finally, good manufacturing practices (GMP) are being used with battery manufacturing processes to ensure maximum reliability. GMP are regulations set forth by the FDA to ensure medical products for commercial distribution in the U.S. are safe and effective. These regulations primarily establish various specifications and controls for medical devices and that they be designed and manufactured under a quality system that can meet those specifications. Medical firms that fail to comply with GMP may incur fines or risk having their products recalled.

capacity with discharges as low as 37% of full capacity. As users gain confidence in the accuracy of battery gauges, there will be a tremendous benefit to medical professionals.

### **Taking devices to class**

The U.S. Food and Drug Administration has established classifications for about 1,700 different devices in three regulatory classes based on the level of control necessary to assure safety and effectiveness. Most manufacturers rely on battery engineers to tailor battery packs to suit their devices when seeking FDA certification. Knowing the class into which a device may fall may change design inputs.

Class I: General Controls are for simple devices that present minimal potential for harm. General controls include good manufacturing techniques, proper branding and labeling, FDA notification before marketing the device, and general reporting procedures.

Examples run the gamut from such mundane items as tongue depressors to specialized items such as hand-held surgical instruments.

Class II: General Controls with Special Controls are subject to Class I standards, plus special labeling requirements, mandatory performance standards, and post-market surveillance. Class II devices must perform as indicated and not injure or harm patients or users. Devices in this class are typically non-invasive and include items such as x-ray machines, infusion pumps, and surgical drapes.

Class III: General controls and premarket approval. These devices require premarket, FDA approval, and a scientific review because they can be life-supporting or life-sustaining, or can be important in preventing impairment of human health, or can represent a potential for unreasonable risk of illness or injury to patient or user. Devices in this class include replacement heart valves, implanted cerebral stimulators, implantable pacemaker pulse generators, and certain endosseous (intra-bone) implants. Class III devices must include alarm systems and battery backup power source.

These smart fuel gauges can display remaining capacities using a variety of user-interfaces. The most basic is a series of LEDs showing the state-of-charge in 20% or 25% increments. This display is usually activated by pressing a push-button switch. Battery fuel gauges can also communicate directly with host devices so displays can indicate remaining run-time or actual percent-of-full capacity with much higher resolution.

When hospitals or clinics replace batteries "on the clock" – every 6, 9, 12, or 18 months – they often throw away good batteries. This has become a thing of the past with recent developments that let batteries send more accurate information to users, such as identifying good batteries from bad. Improved fuel gauges can actually measure state of health (FCC/Initial FCC) to determine when it is time to replace the pack on an individual basis. New functions can also disable the battery when it is no longer reliable. The number of recharge cycles can be synced with the battery pack's warranty, so users will know when the pack really needs replacing.

Properly implementing sophisticated fuel-gauge ICs lets knowledgeable battery-pack designers develop power sources that are safe, abuse tolerant, and can accurately predict remaining run-time. For medical practitioners, this means when a fuel gauge says 50%, they can be confident the device still has half of its battery capacity remaining.

Battery packs used in sterile environments, such as operating rooms, must withstand sterilizations. It's a tall order because autoclave temperatures and pressures can damage cells. This has led some manufacturers of portable medical devices that must be sterilized to use single-use battery packs.

NiMH packs, when sealed and insulated, withstand autoclave sterilization but it reduces the batteries' cycle life. Alternative sterilization techniques, strongly advised for Li-ion battery packs, include chemical cleaning at lower temperatures or peroxide-gas systems in a vacuum at room temperature. However, these lower-temperature chemical treatment alternatives require proper selection of compatible battery materials that do not degrade when exposed to these environments.

### **Meeting regulations**

Underwriters Laboratory, the organization that oversees electronic device safety, has recently changed its UL 60601, standards for medical electrical equipment. One change requires that battery packs comply with UL 2054 (the battery-pack standard) before certifying the host medical device for UL60601. UL 2054 addresses safety of commercial and household battery packs and says devices must withstand

