

How to make Batteries in Medical Devices more reliable

When rubber stamping is not enough

December 2013

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The approval process to release a new product is getting tougher. New rules are added that increase manufacturing costs and complicate logistics. Once approved and released, few rules apply that oversee continued reliability of the device; the agencies have done their job and the responsibility falls on the user.

To assist in the regulatory approval, device manufacturers pick the best battery from the lot. This satisfies the present but ignores true field conditions. Little weight is placed on battery aging and no models exist that assure good reliability with a less than perfect battery. Reserve energy to support emergency situations is often ignored. Manufacturers account for some but the amount is not specified. Figure 1 suggests a 20% *fade* as part of a less than perfect but still usable battery and 20% for *spare*. This would bring the usable battery capacity from 100% to 60%, a requirement that is too stringent for most applications.

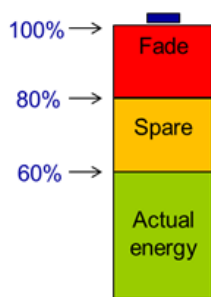


Figure 1: Calculating spare battery capacity

Reserve capacity must be calculated for a worst-case scenario. The allowable capacity range is 80-100%; a spare capacity of 20% is recommended for critical use.

Knowing when to replace a battery is an ongoing concern and date-stamping provides a partial solution. Device manufacturers support this method for obvious reasons; it sells batteries. However, date-stamping has flaws and here is why. Some batteries are in constant use delivering full discharge cycles, others are deployed for infrequent missions, and a third group is mostly on standby. Those in constant use could expire before the appointed time; however, the large majority will last far longer. Premature replacement adds to operational expense and causes environmental concerns.

Some batteries with SMBus call for a replacement after delivering a given number of discharge cycles. This is an improvement as it identifies busy batteries from those on standby but the capacity information is still missing. Capacity is the leading health indicator that specifies when a battery should be replaced.

Li-ion battery can be cycled for 300 times before the capacity drops to roughly 80%. This drop goes mostly unnoticed to the user. Although SMBus batteries feature a state-of-charge indicator, state-of-health is unknown. The capacity may drop to 50% while the fuel gauge still shows 100% after a full charge, skewing runtime expectations. Enforcing tight approval procedures up front is inapt without also tracking battery state-of-health and establishing minimal acceptable capacity level.

Aircraft, vessels, vehicles, pipelines and all types of machinery fall under strict maintenance guidelines. Detailed logs are kept and worn parts are replaced well in advance of a potential failure. Batteries should get the same treatment but they are difficult to control; they escape the scrutiny of inspection and are often labeled “uncontrollable.” Batteries do not demonstrate a visible change as they age and look the same when fully charged or empty, new or in need of replacement. A car tire, on the other hand, distorts when low on air, shows signs of wear, and indicates end-of-life when the treads are worn.

Charging is well understood, but the “ready” light tends to get misconstrued. “Ready” does not mean “able.” There is no link to battery performance, nor does the green light promise a full runtime. Ready simply means that the battery is full.

Batteries always charge completely, even if weak. As the ability to hold charge shrinks, the charge time also shortens because there is less to fill. This causes weak batteries to gravitate to the top, disguised as combat-ready. System collapse is imminent during an emergency when workers scramble for freshly charged batteries. Those glowing on “ready” may be deadwood. (The charge time of a partially charged battery is also short.)

Batteries need more than charge-and-use; proper care is vital for good performance and a long service life. Good care begins by operating them at cool temperatures and charging and discharging at moderate currents. It is better not to run the battery too deep but to charge more often. Lithium-ion does not have memory as nickel-cadmium has, and full discharges are not necessary to prolong life. There is some truth as to why well-cared batteries outperform neglected ones; studies can back this up.

Ideal working conditions are not always possible and batteries should to be checked regularly with a battery analyzer. This keeps a fleet within an acceptable performance level and identifies packs that need replacing. Device manufacturers endorse battery analyzers, knowing that well-performing batteries reflect positively on their devices, a win-win situation for both parties.

In hospitals, medical devices are serviced by *Biomedical Equipment Technologists (BMETs)*, but rechargeable batteries are often outside their field of expertise and special training is recommended. Key issues the BMET must address are:

1. Keep all batteries at an acceptable capacity level. Capacity is the leading health indicator.
2. Establish at what capacity a rechargeable battery should be replaced in a given medical device.
3. Observe the remaining capacity before charging to assure sufficient reserve energy.
4. Apply regular calibrations to maintain coherent state-of-charge readings of smart batteries.
5. Perform spot checks and cycle-tests of batteries offered by new vendors to verify performance.
6. Acquire suitable battery analyzers that perform the required service.

Conventional battery analyzers measure capacity by discharging a fully charged battery while tracking the elapsed time. Rapid-testing would be preferred but this only provides estimated state-of-health values and the degree of accuracies varies with the method used. Medical, public safety and defense organizations still rely on periodic full discharge/charge cycles. This also serves as calibration for smart batteries.

Battery analyzers are available that run in a standalone mode or with PC interface. With software, the computer becomes the host from which all functions are entered. PC-operated systems offer added services, one of which is marking all batteries with a permanent ID number. *PC-BatteryShop™* by Cadex prints these labels in bar code. After scanning, the user simply inserts the battery into the analyzer. Past test results and user information are shown as the service begins. Figure 2 illustrates such a system.

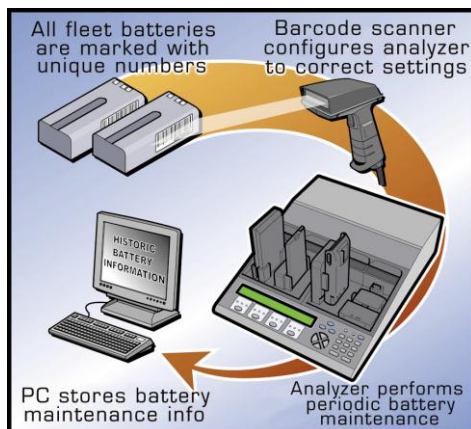


Figure 2: Fleet battery management

Labeling each battery with a unique ID number simplifies battery service. Reading the barcode prepares the analyzer for service. Past logs are displayed on the monitor.

Another service method is attaching a label that displays the last service, due date, capacity and internal resistance. Figure 3 illustrates such a label. The system is self-governing in that a prudent user only picks a battery that has been serviced and meets the capacity requirements. Expired packs are analyzed and upon passing, they are relabeled and returned to service; low capacity batteries are replaced.

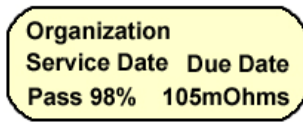


Figure 3: Sample of removable battery label

Basic battery data and service information are contained on a label.

High standards in product safety are important and regulatory agencies are ultimately responsible. However, enforcement practices are not always applied in proportion to encountered hazards and casualties; ease of implementation plays a role. Manufacturers are an easy target and can be shut down for trivial infractions; the public sector, on the other hand, enjoys more freedom.

As an example, casualties are higher from car accidents than the use of a device that does not meet the latest approval. The Pattullo Bridge, a crossing over the Fraser River in the Vancouver area, is narrow and causes many accidents. Excess speed is the main culprit, and a study revealed that only 20% drive at the posted speed limit. Many children drown in swimming pools, and equally serious are children falling from windows with loosely fitted screens. Car manufacturers make great efforts to meet safety requirements, only to have them rebuilt into noisy high or low-riders with oversized tires. Where is the approval agency when rubber meets the road? Highways, private swimming pools and window screens call for more protection, but emphasis on more manageable entities is understandable.

Consumer advocate Ralph Nader (1934) wrote in 1970, "At least 1,200 people a year are electrocuted and many more are killed or injured in needless electrical accidents in hospitals." In 1965, Nader published the book "Unsafe at Any Speed." Regulatory agencies took these concerns seriously and tightened directives, which resulted in safer electrical instruments and cars. With the growing use of portable devices, battery reliability is a new concern.

Summary

Users of portable instruments have learned to take the battery in stride. Posted runtimes mean little without doing a regular battery check. No other specification is as loosely given as that of a battery. Very seldom does a user challenge the battery manufacturer for failing to deliver the specified runtime, even when human lives are at stake. Less critical cases have been heard in court, and won. The battery is an elusive scapegoat that holds special immunity. Running out of power is categorized as an unavoidable event that is beyond control.

Device manufacturers should not carry all the blame; batteries are difficult to test. Advancements in battery diagnostics have been lagging behind other developments, but progress is being made. Future devices will one day include fuel gauges that provide state-of-health readings, offering a significant improvement to present battery management systems (BMS) that only provide state-of-charge readings. Capacity estimations based on the electrochemical battery will give truer performance approximations than relying solely on digital information, a practice that is exercised today.

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About the Author

Isidor Buchmann is the founder and CEO of Cadex Electronics Inc. For three decades, Buchmann has studied the behavior of rechargeable batteries in practical, everyday applications, has written award-winning articles including the best-selling book "Batteries in a Portable World," now in its third edition. Cadex specializes in the design and manufacturing of battery chargers, analyzers and monitoring devices. For more information on batteries, visit www.batteryuniversity.com; product information is on www.cadex.com.