# How to make Batteries in Medical Devices more reliable

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Batteries are critical components in medical devices. As more instruments are computerized and become mobile, systems performance and reliability depends heavily on the battery. Improvements in battery reliability are necessary, and at a recent workshop with Cadex Electronics, the *US Food and Drug Administration (FDA)* in Silver Spring, MD, expressed these concerns about batteries in medical devices:

1. Insufficient quality assurance in medical batteries
2. Lack of knowledge integrating batteries in medical devices
3. Not knowing when to replace the battery

The purpose of the workshop was to find solutions by exploring new techniques in battery diagnostics and monitoring. The FDA is scheduling additional meetings with health care professionals and device manufacturers to which Cadex will again play a supportive role. Brainstorming with specialty groups will explore battery aging and how to assess and manage this phenomenon.

A battery is a corrosive device that begins fading the moment it leaves the factory. Its stubborn and unpredictable behaviour has left many users in awkward situations. According to reports, up to 50% of system breakdowns are attributed to a battery. The *Association for the Advancement of Medical Instrumentation (AAMI)* has identified batteries as one of the top 10 challenges facing biomedical departments in a hospital setting. Some of this can be avoided, but even with the best of care, some packs die early and scientists don't know why. Batteries exhibit human-like characteristics and their state-of-health rests on genetic makeup, environmental conditions and user patterns.

The manufacturer specifies the runtime of a device with a battery performing at 100%, a capacity that only exists for a short time; most batteries in use operate at less. With time, the performance declines and the battery gets smaller in terms of energy storage. Most batteries deliver 300 to 500 discharge/ charge cycles; less on full discharges in a harsh environment.

Most batteries work well in the first year, but the confidence begins to fade in the second and third year. New packs are added and in time the battery fleet becomes a jumble of good and failing batteries. That's when the headache begins. Unless batteries are examined regularly as part of quality assurance, the user has little knowledge on the performance of each pack.

The energy in a battery can be divided into three segments: *available energy*, the *empty zone* that can be refilled, and the *unusable part*, or rock content, that has become dormant and is growing. Figure 1 illustrates these three sections graphically.

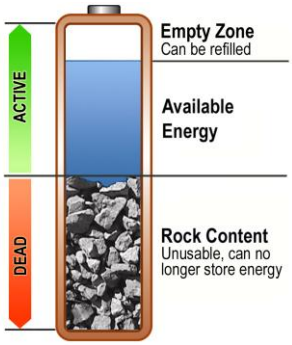


**Figure 1: The three segments of a battery**

A battery stays at full performance for a limited time only. Device manufacturers must assure reliable operation with a battery that is less than 100 percent.

The "ready" light on a charger cannot verify battery state-of-health; it only indicates that the battery is fully charged. As the active space of a battery declines with use, the charge time also decreases. This can be compared to topping a water jug that has been filled with rocks. The shorter charge time pushes weak batteries to the forefront by being ready; they become a hidden disguise for the unsuspecting users placing much faith in the green light.

Let's now address the concerns of the FDA and examine viable remedies.

## 1. Insufficient quality assurance in medical batteries

To meet the strict approval process, manufacturers pick the best battery from the pool. This satisfies the present moment but ignores tolerances in battery performances and capacity losses that develop over time. As part of routine quality check, the manufacturers may check only the voltage and internal resistance of a cell or battery; capacity, the leading health indicator is omitted, and for good reasons. Capacity assessment is complex and a measurement by a discharge/charge cycle is time prohibitive.

*Electrochemical impedance spectroscopy (EIS)* offers promising solutions in estimating capacity and detecting anomalies. This is of special interest to battery manufactures and a close collaboration will be necessary to examine what battery faults EIS can identify. Cadex went further and developed *multi-model electrochemical impedance spectroscopy (Spectro™)*. Spectro ™ is able to read battery capacity non-invasively. Matrices will need to be developed for each battery type to check each cell or battery against the "golden sample." The 15 to 30-second test makes this possible.

The FDA is a sounding board for battery failures and has noted that some implant batteries provide less than half the estimated runtime, hinting to manufacturing deficiencies. A low battery may manifest itself as fatigue in the patient. Doctors are trained to diagnose medical symptoms and are less familiar with the effect of a faded battery. There is also a case where an implant battery shorted and burned the tissues of the patient. As we depend more and more on batteries for our well-being, quality control using advanced technologies will eventually reduce risk and lower medical costs.

## 2. Lack of knowledge integrating batteries in medical devices

Regulatory institutions are concerned that device manufacturers do not place sufficient importance on battery aging. No uniform consumption model exists in assessing capacity; some medical devices are in constant use, others are on standby, skewing aging estimations. Environmental conditions further add to complexity. Safety during the battery life is a further concern that needs attention.

Batteries perform best at room temperature and live longest when stressed only moderately. "Smart" batteries offer a benefit by displaying the remaining charge, but fuel gauge readings can be off. To maintain accuracy, a smart battery needs regular calibration to correct the tracking error between the chemical and digital battery. A calibration should be done every three months or after 40 partial cycles. If the device applies a periodic deep discharge on its own accord, no additional calibration is required.

Even though sealed, some cells include vents to release gases that develop during use or exposure to stressful conditions. The electric toothbrush was brought up as an example where venting was ignored. The engineers specified a waterproof device, not knowing that an alkaline battery produces some gases during discharge. The accumulated gases inside a toothbrush led to an explosion that injured the user.

The modification of the Boeing B787 Dreamliner battery is another example where battery behavior was overlooked. The engineers estimated smoke events on the Li-ion battery to occur only once in 10 million flight hours, but two packs failed on new aircrafts in less than 100,000 flight hours. The mandated battery modification involves isolating individual cells to avert a chain reaction should one overheat, placing the battery in a steel container capable of withstanding a fire without damaging the surrounding areas, and adding a one-way vent to release gases from a burning battery to the outside. Designers of medical devices can learn from this experience.

## 3. Not knowing when to replace the battery

A battery is a consumable component that gradually loses performance over time. Unlike a car tire that can be inspected for wear and tear and replaced when the treads are low, the battery is a black box that does not change color, size or weight; it quits on its own time table. Device manufacturers must make the users aware of the symptoms of a weak battery and hint to battery replacement policies. This is not well understood in the medical industry and needs attention. When the author of this article asks users, "At what capacity do you replace the battery," most shrug their shoulders and say, "I don't know."

Besides assuring sufficient energy reserve, medical device users must also plan for a worst-case scenario. Although manufacturers do include some reserve, it became apparent at the FDA meeting that this is not clearly defined. Energy reserve as part of battery aging and worst-case scenario varies by application. Critical missions need tighter requirements and such a battery might need replacement sooner than for less demanding uses where an unexpected failure can be tolerated. Figure 2 provides tolerances for *fade* and *spare*, bringing the usable battery capacity to 60% in worst-case scenario.

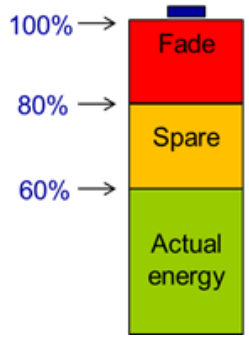


**Figure 2: Calculating spare battery capacity**

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

Some public safety organisations use the highest performing batteries for critical applications and pass packs with shrinking capacities to less demanding roles where replacements are on hand should a failure occur. Placing batteries into different tier levels allows economical use of batteries without sacrificing reliability. Performance evaluation based on capacity can only be done reliably with battery maintenance. Neither date-stamping nor the use of a smart battery provides reliable alternatives. (Cadex (www.cadex.com) specializes in battery analyzers and management systems.)

## Summary

Battery diagnostics has not advanced as quickly as other technologies, but progress is being made. Experts predict that EIS will lead the path and the results at the Cadex laboratories are promising. A growing number of hospitals and paramedics are also taking the proactive approach towards battery maintenance. Servicing a large battery fleet on automated battery analyzers takes less than one hour a day and the payback is estimated at one year on battery savings alone. Increased risk management and reducing the environmental impact of discarding batteries too early are added bonuses. Utilizing new technologies in battery management will make a noticeable change in the reliability of medical devices.

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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.