

Battery Risk Management in Healthcare

Weak Link in Healthcare

Batteries play a pivotal role in the performance and reliability of medical devices. As more portable devices are deployed in healthcare, the reliance on the battery grows, so does the need for robust battery management standards and practices.

This is not happening. The Association for the Advancement of Medical Instrumentation (AAMI) rates battery management as one of the top 10 challenges for hospital's biomedical departments. An US FDA survey says that "up to 50% of service calls in hospitals relate to battery issues."



The FDA has identified three problem areas with batteries in healthcare:

- 1. Deficiency in quality assurance in batteries by device manufacturers
- 2. Lack of understanding in battery system integration
- 3. Not knowing the end of battery life

To develop awareness, the FDA organized the *Battery-Powered Medical Devices Workshop* in July 2013. This resulted in an agreement to establish standard practices to care for rechargeable batteries in medical devices. A committee will be created to carry out this mandate.

A battery has a relatively short service life and must be treated like any other serviceable part in a medical device. When asking users of a battery-operated medical devices, "When should the battery be replaced?" no clear answers are given. Without a strategic management plan, batteries are often changed too soon; others are allowed to die in the device, causing system failures.

Battery Date-stamping

Device manufacturers promote date-stamping as a means to replace a battery. This may rotate inventory but it adds to needless time restrictions along the lines of expiring isotope in nuclear medicine. Batteries have improved and live longer; they also carry a higher price tag. This makes reliance on date-stamping alone ineffective and expensive. Here is why.

Battery life is governed by usage, not time. Date-stamping fails to identify batteries that fade prematurely due to heavy usage. To compensate for early failures, device manufacturers mandate a more strenuous replacement policy and a two-year time span is now widely used.

Nickel-based batteries provide about three-years of service; Li-ion five. Storage characteristics have also improved. Under-usage in healthcare is more common than over-usage, leading to discarding a large pool of good batteries needlessly.



Paradox

Date-stamping has not solved the battery problem but raises a new question. Discarding unchecked batteries escalates cost and harms the environment. A manager at DOE said that every year roughly one million usable lithium-ion batteries are sent in for recycling with most having a capacity of up to 80%.

Batteries are dumb and need supervision

The ready light on the charger does not mean "able;" it only says that the battery is fully charged. Faded batteries charge quicker than good ones and are picked as combat ready. A fuel gauge always shows 100% after each charge even if the capacity has dropped in half. Capacity is the leading health indicator that governs the end of battery life.

Introducing Battery Management

Healthcare organizations are acquiring battery analyzers, such as the Cadex C7400ER, to service medical batteries. These analyzers assure that all fleet batteries stay within a capacity of 80–100%. Knowing the performance of each pack improves reliability, reduces operational cost as each battery can be fully utilized and assists in troubleshooting as fewer devices are sent for repair.



Cadex C7400ER battery analyzer services four batteries of choice with custom battery adapters

Implementing Battery Management

Follow these easy steps when setting up battery management: [1] Choose the participating batteries, [2] set risk category, [3] develop service protocol, [4] purchase equipment, and [5] commence service. When implementing the program, consider these unique requirements:

Runtime Establish a minimal acceptable capacity; 80% is typical for medical batteries. A

lower capacity threshold may be used for less critical uses and training purposes.

Spare Capacity Spot-check spare capacity after a mission. A battery should have 20% spare to cover

unexpected activities. Advanced battery analyzers (Cadex) display the spare capacity

by applying a discharge before beginning with a full battery assessment.

Usage Patterns As part of a service protocol, service packs in daily use once every 1–3 months.

Batteries in sporadic use may get by with a 3–6 month service interval; standby

batteries should be checked at least once a year.

Test Methods: Battery management must include capacity evaluation. Impedance check, reading the

digital battery and date-stamping do not provide a reliable performance assessment. A

full service with the battery analyzer also calibrates the smart battery.

Aging Trend: Batteries do not die suddenly but follow a predicted decline based on stress and depth

of discharge. Performance analysis supports retirement planning and educates device

manufacturers in battery system integration.

Meeting the Objectives

Escalating battery costs must be brought under control without affecting reliability and lowering therapy delivery. Battery management solves this by offering battery capacity assessment and sharing the data with management. Automated systems, such as Cadex, reduce labor times to roughly 30 minutes per day. Battery analyzers also provide incoming inspections and verify battery performance of new vendors.

Battery problems need no longer be part of AAMI's 10 top challenges, nor should they cause half the service calls as the FDA states. Batteries can be trained and tamed.



ISO 9001, ISO 13485

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