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WHITE PAPER

Improving Battery Quality and Patient Outcomes for Medical Devices

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Because of the extreme risk associated with even minor product quality issues, it is imperative that medical devices operate as designed, for as long as defined in the product specifications. A critical component that often defines the longevity of a medical device, battery quality and performance must be verified in nearly all medical products in which they are used. Batteries play a critical, lifesaving role in a wide range of medical applications. Many electrical medical devices, such as pacemakers and cardiac monitors, are surgically implanted into the patient's body, and a premature battery failure could lead to open heart surgery or unexpected heart failure. Battery modules and packs used in medical applications also are often critical to patient safety, and battery quality must be rigorously measured and verified to ensure proper operation of lifesaving medical equipment.

Batteries include:

- **Cells**—Cells serve as fundamental battery pack building blocks and are individually tested to assess performance and capacity.
- **Modules**—Modules are groups of cells connected in series and/or parallel configurations. They are tested to evaluate overall performance and capacity.
- **Packs**—Packs are collections of modules interconnected to form a complete battery system. They undergo testing to assess performance, capacity, and safety. In some designs, modules and packs are synonymous.

While small medical devices will be powered by single cell batteries, larger devices will typically use modules or packs. In addition to battery pack electrical characteristics, the physical design must undergo validation. Module assemblies undergo design verification tests (DVTs) to ensure that the battery design meets specified requirements. These tests may include power cycling, endurance testing, and HALT testing, as well as testing of electrical characteristics such as open circuit voltage (OCV), electrochemical impedance spectroscopy (EIS), and alternating current internal resistance (ACIR) testing.

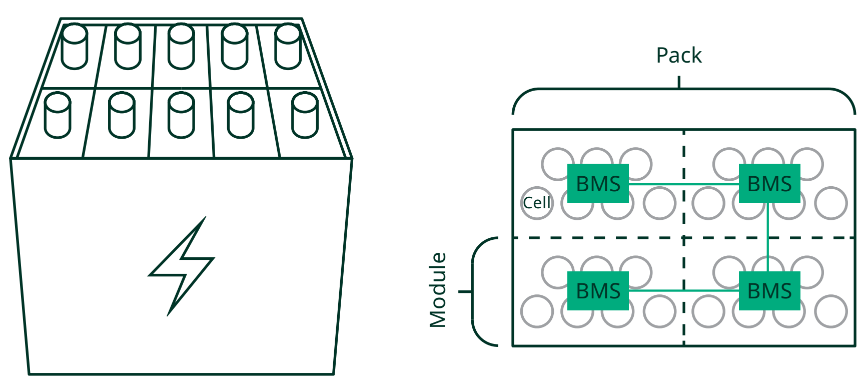

FIGURE 1

Battery Components

Battery Test Challenges

Ensuring the continued functionality of batteries intended to be deployed in medical devices requires comprehensive testing to assess various performance parameters while, in many cases, simulating the real-world conditions where the battery will be deployed. This typically involves battery design quality analysis, durability and performance of a battery design across a range of environmental conditions, and manufactured battery quality at the time of assembly. Test teams must validate their designs and manufactured batteries against the following requirements:

- **Safety**—The battery must maintain safety under all specified operating conditions. In the event of failure, it should gracefully handle all failure modes, whether caused by manufacturing defects, such as faulty cells or weak welds, or due to battery damage.
- **Performance**—The battery must meet performance design objectives, including charge time, peak energy transfer rates, and thermal stability over its operational lifespan.
- **Longevity**—The battery should retain a specific capacity over cycles defined by expected usage patterns and duration (for example, retaining at least 80 percent of the original capacity after 2,500 charge cycles).

Battery characteristics necessitate duplicate test cells for conducting long-term tests, which can be challenging to accelerate. This poses difficulties in managing the systems, test laboratories, and the resulting data. The evolving nature of test requirements increases the risk associated with closed, vendor-dependent test systems in terms of time to market and cost.

During the battery manufacturing, there is an inherent tradeoff between battery testing coverage and manufacturing throughput. It is critical to identify areas of potential failure in the most efficient method possible to ensure enough manufacturing volume to meet market demand. Balancing throughput and test coverage during manufacturing can avoid costly recalls while meeting market demand in a timely manner.

Battery Component Testing Methods

Using software-defined instruments can reduce overall test equipment costs by reusing equipment and measurement IP across the new product development process, including validation and production testing. Software-defined instruments provide flexibility in testing; a single piece of equipment performs multiple functions which can then be leveraged to standardize hardware across an organization. In addition, software-defined instruments make it easy to automate tests to minimize manual measurements and support growing production volumes.

With this flexibility, teams can choose hardware based on voltage, current, power, and timing requirements, while the remaining instrument behavior can be defined through software. For instance, source measurement units (SMUs) can function as voltage or current sources controlled through software for a wide range of measurements. The timing and synchronization capabilities of PXI modules facilitate advanced functionalities such as waveform generation and acquisition for making complex measurements such as electrochemical impedance spectroscopy (EIS), cycle testing (Coulomb counting), and alternating current internal resistance (AC-IR).

By changing the software, the same instrument can switch between different test methodologies. In addition to its parametric measurement capabilities, these instruments can run simulations using hardware-in-the-loop (HIL) software like NI VeriStand and perform test automation using NI tools such as LabVIEW and TestStand.

Cell Test/Measurements

Ensuring battery cell quality is of the utmost importance in many lifesaving medical devices. A battery failure in a pacemaker could lead to an earlier than expected heart surgery or heart failure in a patient with critical cardiac health needs. To ensure battery cell quality, we can run various tests to determine potential failures before they reach the patient. These tests include:

- **Open-Circuit Voltage (OCV)**—OCV represents the most fundamental testing method and can be conducted using various instruments based on specific measurement requirements. A commonly used instrument is a digital multimeter (DMM) due to its superior accuracy and isolation capabilities, especially when measuring large battery stacks. Although a DMM can support high-density configurations, it is often combined with a switch to enhance instrumentation density. OCV serves multiple purposes including determining the state of charge (SoC) of a battery cell, identifying potential cell issues and monitoring long-term cell performance.

  OCV measurement is a nondestructive approach that involves measuring the voltage of a battery cell without a load connected. Deriving SoC from OCV can be challenging due to the relatively flat discharge/charge curve in lithium chemistries. Charge counting often proves to be more reliable for cells, modules, or packs for accurate SoC determination.

- **Capacity**—Performing capacity testing on cells, modules, or packs requires utilizing current sources/sinks for charging and discharging the device under test (DUT). Modern lithium chemistries typically undergo capacity testing using constant current charge and discharge profiles for most of their capacity, transitioning to voltage control only during the final few percent of the charge/discharge process. The capacity is quantified as the integral of the current or voltage over the charge/discharge time, which can be calculated by the application software executing the test.

  The overall capacity is usually expressed in watt-hours (Wh) or ampere-hours (Ah), and discharge rates typically are indicated as a ratio relative to the cell/pack capacity. For example, a 1 Ah cell tested at 1A is referred to as a 1C rate test. Since the charge and discharge rates depend on the overall capacity of the DUT, the power requirements can vary significantly.

  For instance, single cells may require around 5 watts, while large packs may necessitate multiple kilowatts of test capability. Depending on the power requirements of the DUT, testing can utilize PXI SMUs, RMX source/loads, or large regenerative supplies from NH Research (NHR) for cell, module, or pack testing, respectively.

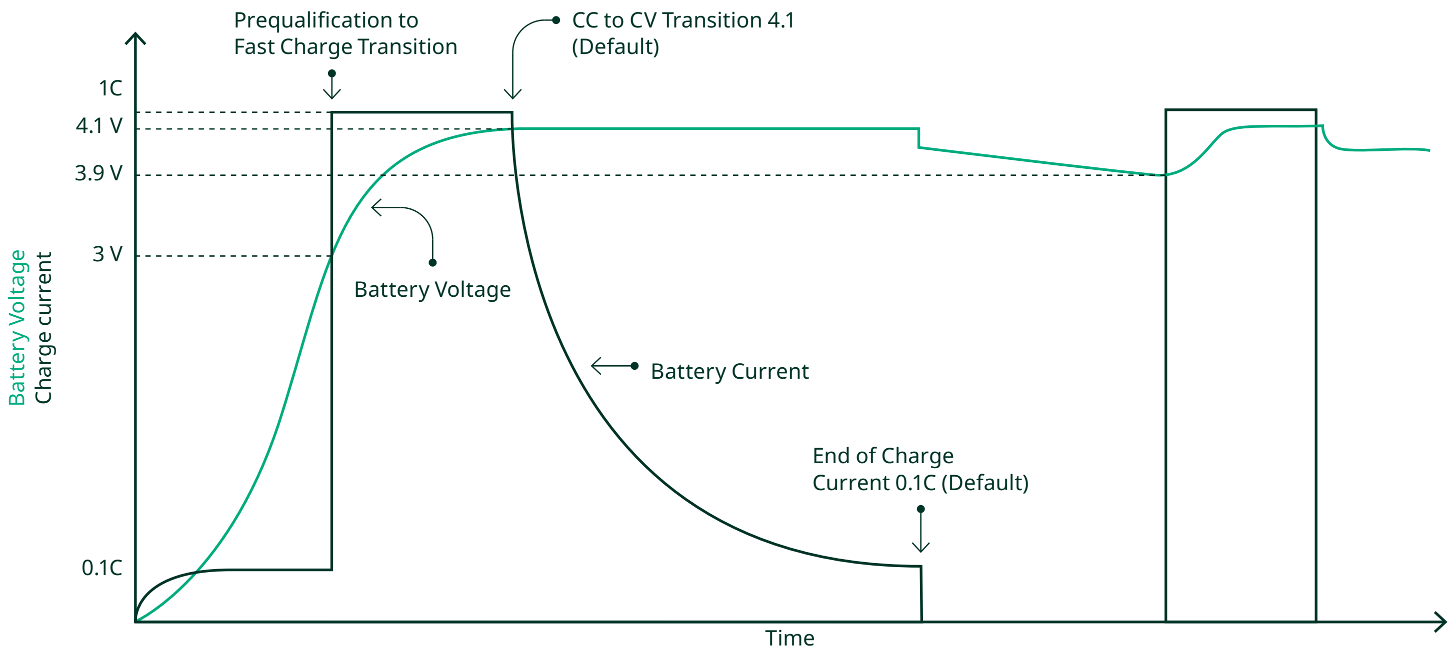

FIGURE 2

Example Charge Profile

- **Cycle Life**—Cycle life is the number of charge and discharge cycles a cell can undergo before its performance deteriorates below acceptable limits or it fails. Cycle-life testing involves analyzing the cell capacity as it undergoes repeated cycles under different conditions. Often, cycle life is characterized by the number of cycles required to reach 80 percent of the original capacity at a specific depth of discharge (DoD) and rate.
- **Voltage Drop Analysis**—Voltage drop analysis examines the magnitude of voltage drop that occurs when a cell is discharged at a specific rate. Teams can use various loads, such as PXI SMUs, RMX electronic loads, or NHR regenerative supplies based on the power requirements of the test setup. For precise and reliable measurements, it is crucial to configure the loads with remote sense capability. **Remote sense** helps ensure accurate voltage measurements by compensating for any voltage drops that may occur along the measurement leads.
- **AC-IR**—AC-IR analysis provides a nondestructive method for evaluating the health of a battery cell. This test involves applying a small AC current to the cell and measuring the resulting voltage drop. AC-IR is particularly important when assembling a module or pack by matching cells, as cells with similar parameters can distribute the load evenly, resulting in improved cycle life and overall performance. Typically, this test is conducted at the cell level and requires relatively low power levels. SMUs are well-suited for performing these measurements, as they can generate various voltage/current waveforms while accurately measuring the corresponding response. The internal resistance is then determined using Ohm's law based on the analysis of these waveforms.

- **Electrochemical Impedance Spectroscopy (EIS)**—EIS involves analyzing the frequency response of a sinusoidal voltage stimulus applied to a battery cell. Examining the phase of the resulting current response reveals valuable insights into the electrochemical properties of the cell. EIS finds applications in research, development, and quality control for electrode degradation, electrolyte changes, and phenomena detection at the electrolyte-electrode interface that can impact battery performance and longevity.

  While EIS commonly is used in cell research and development, it also can serve as an effective screening test in cell production. EIS measurements typically utilize specialized equipment, such as an impedance analyzer. However, NI's SMUs can provide equivalent measurements due to their ability to generate and acquire waveforms from the cell under test. NI's software-defined instrument approach extends the test capabilities of existing hardware, making EIS measurements possible without the need for additional dedicated equipment. EIS produces a Nyquist (Cole-Cole) plot, which is a graph that shows the impedance of a system at different frequencies.

  Impedance is a complex number that includes resistance and reactance. With the Nyquist plot, teams can analyze the different physical phenomena that occur within a battery, such as electrolyte resistance, charge transfer resistance, and diffusion resistance. The degradation level of a battery also can be evaluated by analyzing the charge transfer resistance on the Nyquist plot. For example, Figure 3A shows a Cole-Cole plot from an EIS test performed on a Lithium-ion battery with a frequency sweep from .1 Hz to 1 kHz; Figure 3B shows a high-frequency EIS test sweep from 1.1 kHz to 500 kHz.

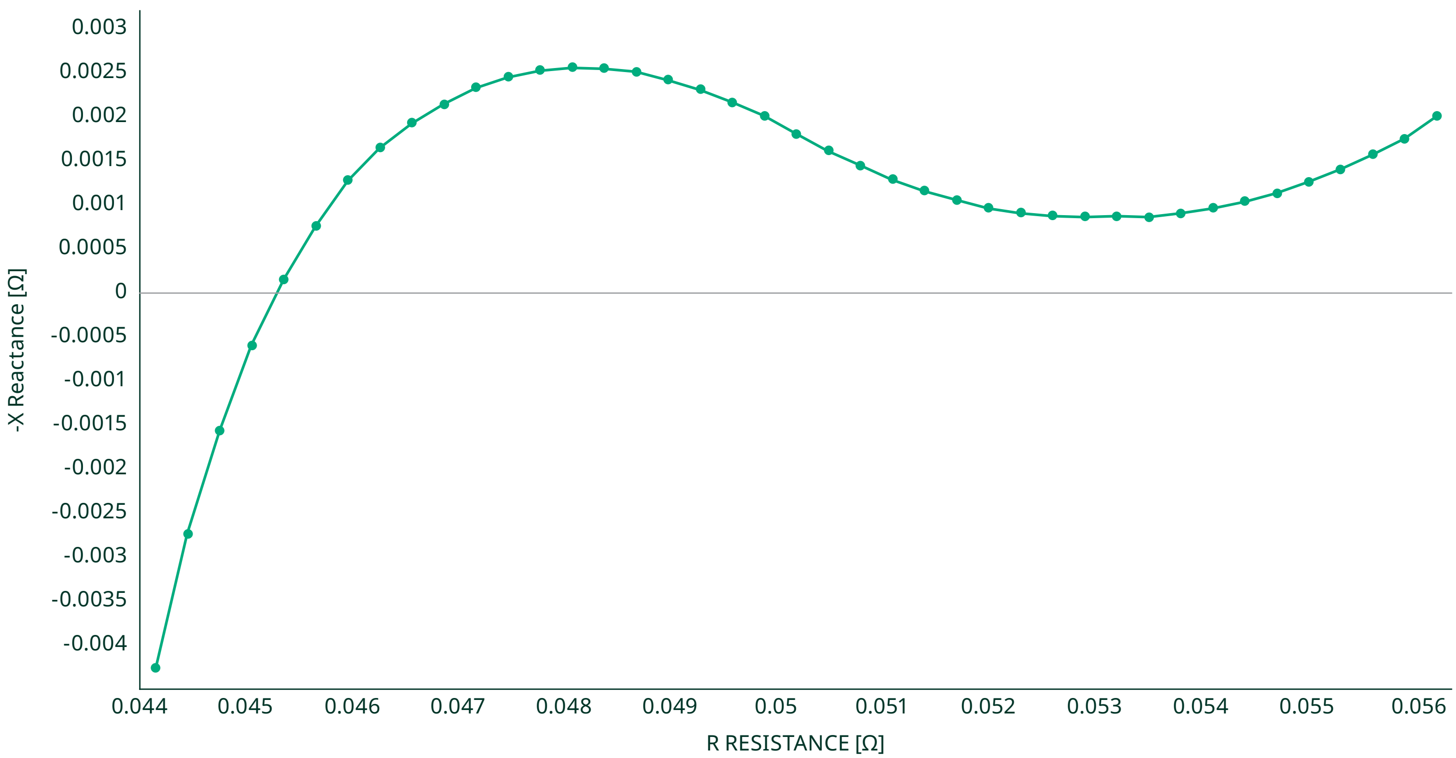

FIGURE 3A

An actual Cole-Cole plot produced by low-frequency EIS test of a lithium-ion battery using an NI PXI instrument.

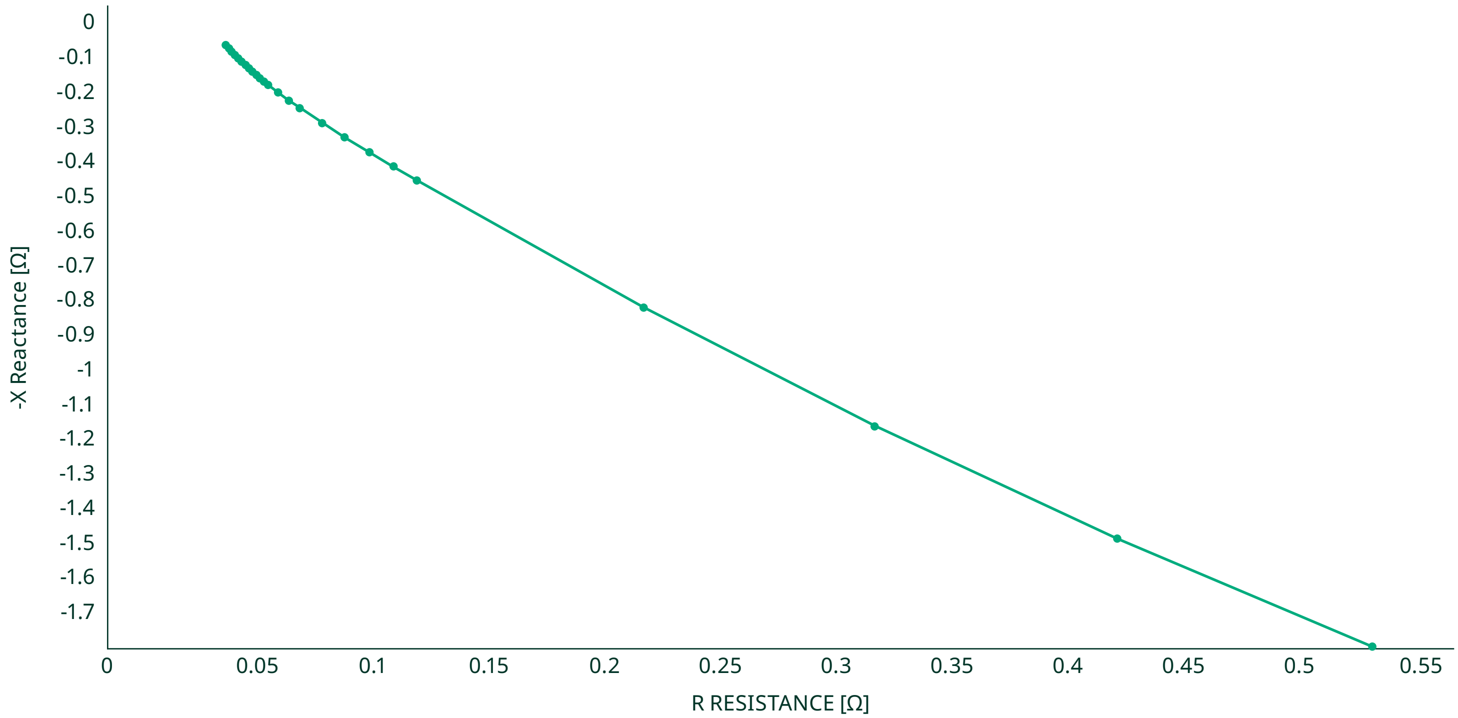

FIGURE 3B

An actual Cole-Cole plot produced by a high-frequency EIS test of a lithium-ion battery using an NI PXI instrument.

Assembly Testing

Once the individual cells have completed the qualification process, they may be assembled into a module or pack. The module/pack undergoes rigorous testing to ensure its compliance with specified requirements based on the rating of the module/pack. While some of the tests conducted at the cell level can be repeated on the assembled pack, additional tests are necessary to address the increased complexity and potential failure points introduced during the assembly process. In some cases, limited testing may be conducted to preserve cycle life. However, common testing procedures include:

- **Pack Mechanical Construction**—Construction validation ensures that the pack meets design requirements and prevents assembly-related failures (for example, cell tab weld failure).
  - **Battery Cell Weld**—Welding is a common way to join battery cells, aiming to establish a robust, low-impedance connection that maximizes current capacity and strength while keeping the weight minimal. While destructive testing evaluates weld parameters, nondestructive testing is crucial for pack assemblies. Thus, impedance measurements across the welds serve as an effective nondestructive evaluation technique. Accurate measurements can be challenging due to the typical milliohm or microohm range of battery welds. To enhance measurement accuracy, applying higher currents can assist in evaluating the weld impedance. Using a PXI SMU (Figure 4) offers higher current capabilities than a standard DMM for resistance measurements. Alternatively, a DMM, along with an external current source such as an RMX supply (Figure 5), provides a greater excitation current to improve the accuracy of impedance measurements. In either approach, a four-wire measurement configuration ensures that lead resistance does not introduce any adverse effects that could affect result accuracy or reliability.

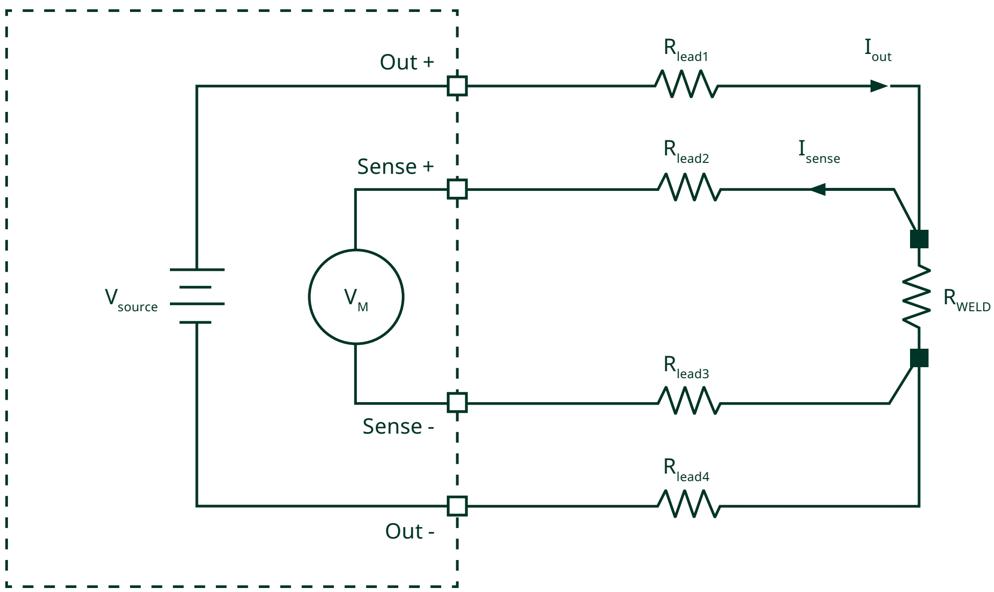

FIGURE 4

An SMU configured with remote sense allows a single instrument to perform a high-current four-wire resistance measurement with a single instrument. Higher excitation currents are required to accurately measure low-impedance welds.

FIGURE 5

Using a DMM combined with external current excitation enables accurate low-impedance battery weld measurements, essentially providing a high-current, four-wire measurement using two pieces of test equipment.

- **Pack-Level Failure Testing**—Comprehensive testing identifies potential failure modes. Depending on the fault tolerance of the pack, tests should measure its ability to continue operating following a failure (examples include shorted cell, high cell impedance, and weld failure).
    - **Shock and Vibration**—Typically, components undergo functionality tests both before and after subjecting them to rigorous shock and vibration tests conducted on shaker tables. These tests simulate the levels of stress that the components are anticipated to endure. While it is uncommon to perform functional tests while devices are undergoing testing on the shaker table, it is standard practice to monitor the test process to ensure the accuracy of the test profile. NI offers several PC- and PXI-based systems with plug-and-play DAQ devices with fixed functionality or configurable systems that let you mix and match hardware. Combine that with FlexLogger™ software, NI's no-code data acquisition software for validation and verification test applications, to monitor the test process to ensure the accuracy of the test profile.

- **Cell Matching for Pack Assembly**—Before assembling cells into a pack, it is crucial to characterize each cell individually to achieve optimal performance and longevity of the pack. Matching the capacity and impedance of cells within a pack is vital to ensure uniform energy utilization and balanced loads. This approach prevents excessive strain on individual cells, avoids capacity degradation, and extends the cycle life, thereby preserving the overall performance of the pack. Capacity and internal resistance tests are conducted at the cell level to gather relevant data, which is then utilized to strategically position cells within the pack, optimizing their arrangement for improved performance.
- **Initial Pack Balancing**—Achieving balance within the pack is crucial to ensure that all cells contribute equally to the overall power output. While it is possible for an unbalanced pack to self-balance over multiple charge cycles, the pack will not reach its full capacity until proper balancing is accomplished. To prevent an unbalanced state after assembly, individual cells can undergo top balancing. This process ensures that cells are fully charged and brought to the same state of charge before pack assembly, thereby promoting balance and optimal performance of the pack.

NI's Approach to Battery Testing

The NI approach to medical device battery testing aims to optimize organizational efficiency and improve the quality and reliability of batteries used in medical devices by using integrated hardware and software tools and test automation so that engineers can make data a key part of their test strategy. Using data acquisition, signal conditioning, control systems, and automated test software across the product lifecycle are integral parts of this approach. By incorporating data management and analytics into the test of battery cells, modules, and packs, it becomes easier and more cost-effective to identify and resolve issues before they reach the patient. NI provides a comprehensive solution that streamlines the testing process, helps ensure quality and reliability, and ultimately improves product quality and minimizes the risk of unexpected field failures.

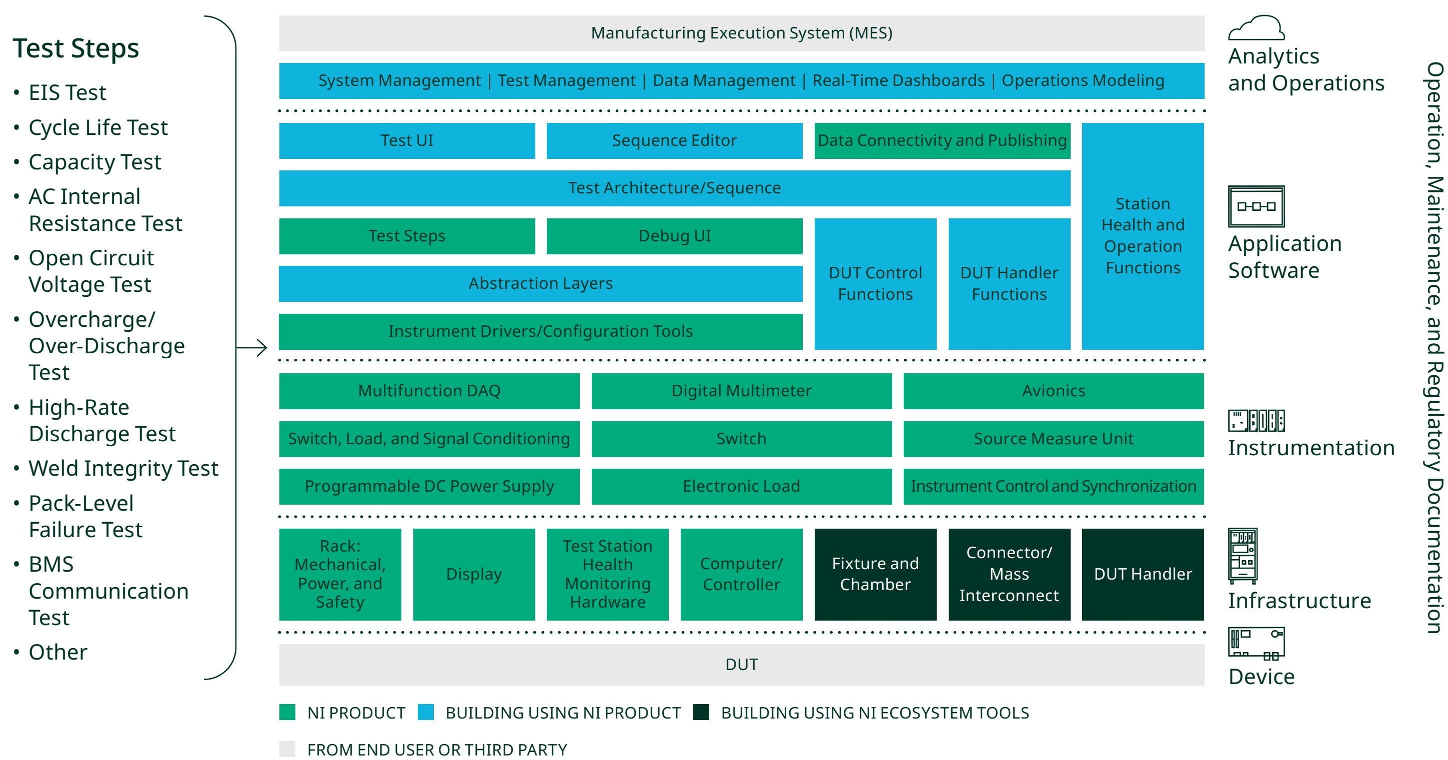

FIGURE 6

NI's Battery Test Approach

NI offers a comprehensive suite of battery testing solutions to test medical device batteries. Based on NI's expertise in data acquisition, automation, and visualization, medical customers can leverage NI's solutions to test batteries at all stages of development, from early prototyping to final qualification.

NI's battery testing solutions include:

- **Modular and expandable I/O**—Add measurement channels to expand with minimum incremental cost per channel and quickly add mixed measurements.
- **Scalable power options**—Access a variety of power envelope coverage for range of voltages.
- **In-chamber measurements**—Use rugged, synchronized, IP-rated measurement modules and thermal chamber control for temperature and humidity profile test execution, as well as other DUT measurements like strain, voltage, current, or vibration.
- **Digital interface communications**—Integrate digital DUT control communications standards and custom protocols to interface with application-specific requirements.
- **Enterprise management**—Create customized data dashboards with the right information for the right people, to take the right actions to maximize utilization and uptime, monitor test systems, and manage the test facility assets.

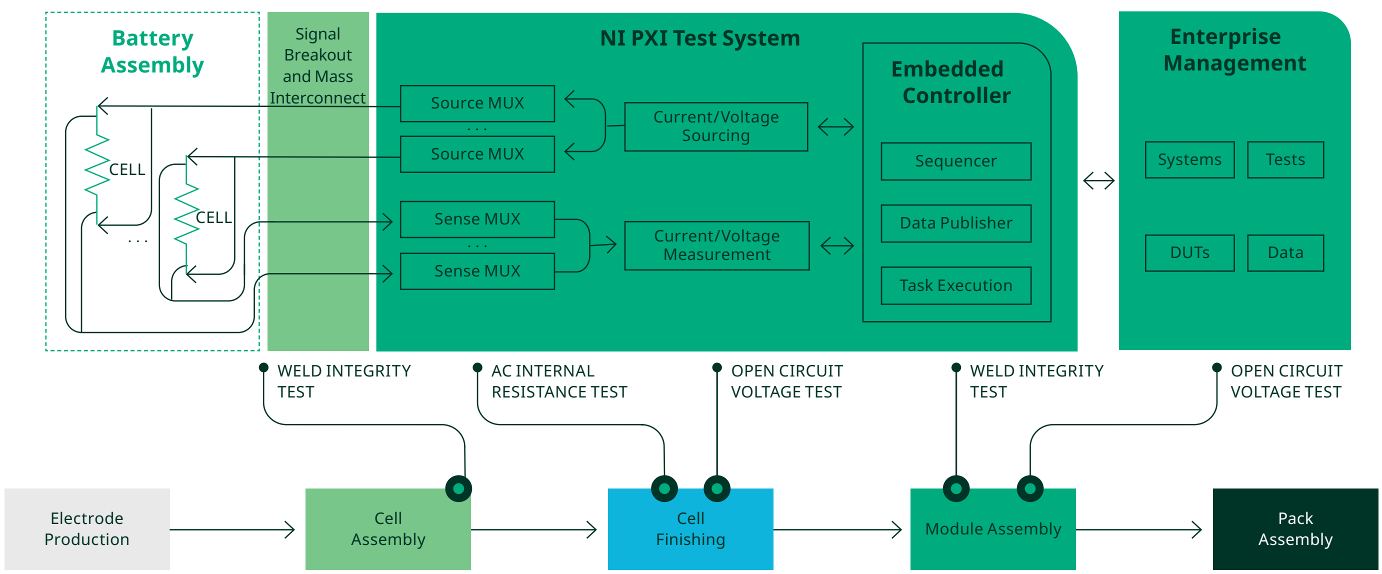

FIGURE 7

Battery Cell and Module Solutions

Choose from multiple solutions based on your testing needs:

- PXI provides the most compact and high-performance form factor to pack more test and scale up production volumes.
- The SMU and LCR Meter provide repeatable and precise measurement and current sourcing for AC-IR and weld integrity test.
- The **programmable power supply and electronic load devices** provide the DC power and power-sinking capabilities to simulate a range of load conditions.
- The DMM performs fast and precise voltage measurements for OCV and weld integrity test.

- NI's multiplexers effectively scale the system to 32 or 64 channels, depending on the type of test, for maximum coverage in a smaller footprint.
- NI CompactDAQ hardware offers synchronized mixed sensor measurement monitoring.
- Direct integrate with test software such as TestStand, Switch Executive, and SystemLink™ software for enterprise data and systems management.

NI's Battery Test Solutions Advantages

There are several benefits to using NI's battery testing solutions, including:

- Test speed to meet production volume with maximum precision and control for long test runs
- Cost-effective, precise, and high-throughput PXI configurations using SMU, LCR meter, DMM, and high-speed multiplexers
- Scalability of number of channels depending on the test type per system in a small footprint
- Test execution and insight gathering improves uptime, monitors test assets, and performs preemptive test station maintenance
- Service programs ensure maximum equipment availability and uptime

Conclusion

Battery quality in medical devices and instrumentation is critical to ensure the safety and efficacy of the medical device for the patient. One failure of a battery in a deployed medical device risks loss of life for the patient, and it can mean the difference between leading the market and struggling to compete. To combat these pressures, best-in-class engineering groups are standardizing their approaches to test with reusable frameworks of COTS components. This is helping them accelerate development while ensuring future scalability.

Serving manufacturers directly and through integration partners, NI has been a leader in test for more than 40 years. NI's battery testing solutions offer a comprehensive and flexible approach to testing medical device batteries at all stages of development and manufacturing. These solutions ensure that lifesaving medical devices and systems are tested properly and that the results are reliable enough to meet the strict regulatory standards of the medical industry. NI's platform approach to test combines high-performance instrumentation with test development, sequencing, and management software tools to meet specifications, time-to-market schedules, and budgets. Let NI help you standardize your processes, systems, software, and data infrastructure to build a strong foundation for digitalization technology, such as analytics, that make best use of your data to improve product and operational performance.

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