



A Case Study in MedTech Product Development

ENGINEERING DEFIBRIO'S LIFE-SAVING INNOVATION

THE FIRST AED POWERED
BY A SMARTPHONE



ENGINEER THE IMPOSSIBLE IN HARDTECH

www.Andrews-Cooper.com



CHALLENGE | A CRITICAL GAP IN AED EMERGENCY CARDIAC RESPONSE

Sudden cardiac arrest (SCA) requires immediate intervention—ideally within 3–5 minutes—to maximize survival chances. Traditional automated external defibrillators (AEDs) are often inaccessible when needed most, leaving a critical gap in emergency response.

Defibrio set out to change this by developing the world's first smartphone-powered AED system. Their vision required integrating custom hardware, real-time rhythm recognition software, and an intuitive mobile application—all within a compact, portable form factor.

Partnering with Andrews Cooper (AC), Defibrio leveraged multidisciplinary engineering, regulatory expertise, and strategic industry partnerships to bring this life-saving device to reality.



SOLUTION | PORTABLE AED POWERED & GUIDED BY A SMARTPHONE FOR PERSONAL ACCESSIBILITY

Transforming Defibrio's vision into a fully functional, smartphone-powered AED required a multidisciplinary engineering approach to ensure the device *met their requirements*, was *intuitive* and *easy-to-use*, and *ready for third-party testing* and *regulatory scrutiny*. Key requirements included:

- Power Conversion**
 Extract sufficient energy from a smartphone battery to deliver a therapeutic, high-voltage defibrillation shock.
- Real-Time Heart Rhythm Recognition**
 Design a multilayered software solution to accurately identify shockable heart rhythms in real time via a smartphone application.
- Affordable Ruggedization**
 Design a durable device with components capable of high performance and reliability across diverse use environments, including extreme temperatures and wet conditions, while making it affordable for broad consumer adoption.
- Regulatory Compliance**
 Engineer, test, and document development for FDA Class III and EU MDR requirements while adjusting novel innovations for legacy AED regulations not written for a smartphone-integrated solution.



Every aspect of the device—from power conversion and front-to-back-end software to usability and manufacturability—needed to be designed and developed seamlessly while meeting stringent performance and safety requirements. Through iterative design, rigorous testing, and strategic collaboration, the development process balanced technical innovation with real-world feasibility at every step.



With over 25 years of expertise in MedTech product development, **AC** specializes in engineering complex, high-risk medical technologies from concept to commercialization.

As a leader in R&D, product development, hardware testing, and custom manufacturing automation, AC partners with ambitious companies to accelerate breakthrough innovations while navigating the stringent demands of medical device regulation.

From a multi-disciplinary engineering approach and proven project management framework, AC derisks development, integrates hardware testing, and ensures products are verified, manufacturable, scalable, and market-ready.

Defibrio is a MedTech innovator committed to expanding access to life-saving defibrillation. Defibrio reimagined portable defibrillator technology to create the first smartphone-powered AED, transforming how—and where—emergency cardiac care happens.

"The power to save someone's life is already in your hands."



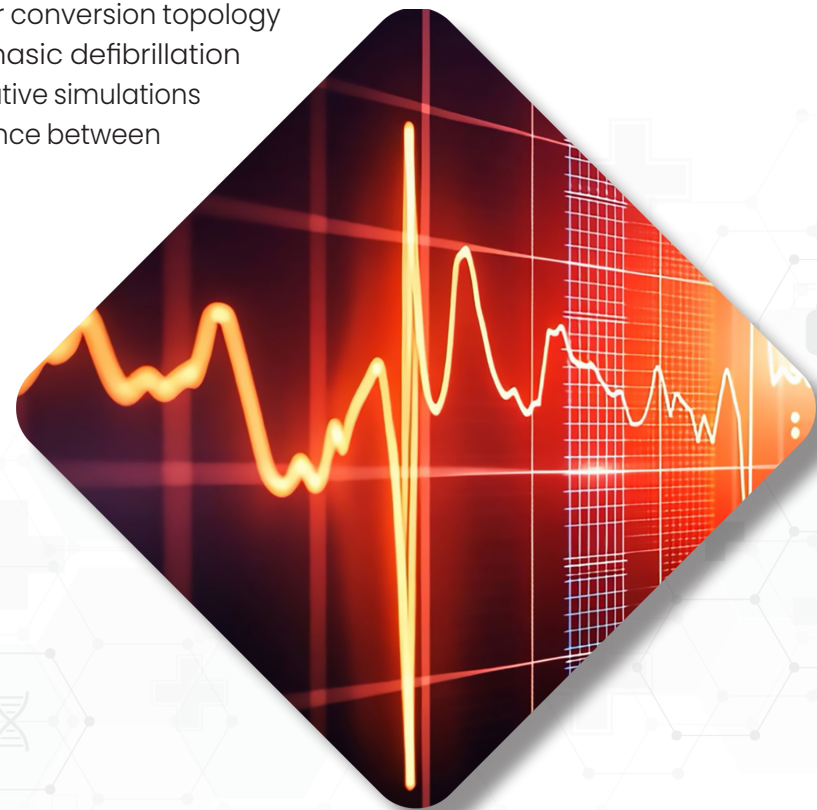


SOLVING THE POWER CONVERSION & MINIATURIZATION CHALLENGES

At the core of Defibrio's Product Development (PD) innovation was the challenge of converting a smartphone battery's low-voltage output into a high-voltage therapeutic shock—without external power sources or bulky capacitors.

Custom Energy Transfer System

AC engineers customized the AED's power conversion topology to step up low-power energy into a biphasic defibrillation shock. Early-stage failure analysis and iterative simulations optimized efficiency while ensuring a balance between energy density, durability, and size.



Key engineering efforts included:

- Evaluating capacitor technologies to identify components that met stringent requirements for charge retention and discharge speed.
- Designing and hand-winding transformers to validate volumetric fit, thermal management, and energy transfer characteristics.
- Integrating rapid bench testing and iterative redesigns, ensuring each prototype iteration refined energy delivery performance.

"Through careful planning and coordination, experienced teams tackled crucial deliverables from engineering development, regulatory/quality, manufacturing, and clinical sectors. Achieving success meant ensuring everyone stayed aligned and focused on the objective."

— Jim LeBaron
Senior Project Manager
AC Product Development



Early Lab Testing & Verification

Early testable units were sent to Massachusetts General Hospital's symposium—**MD PnP – Getting Connected for Patient Safety™**. Clinicians assessed the AED's ability to generate a therapeutic shock and its alignment with emergency care protocols, providing early verification of proof-of-concept viability.

Optimizing Form Factor & User Experience

Designing an AED compact enough to integrate with a smartphone required close collaboration between mechanical engineers, product designers, and user experience (UX) specialists. Partnering with **Motiv**, a Boston-based product design firm, ensured that every aspect of form factor design and usability supported real-world emergency deployment, including:

- Refining the ergonomic placement of electrode pads through industrial design evaluations, ensuring intuitive positioning for non-technical users.
- Designing UX interactivity with the device for rapid deployment, minimizing steps between deployment and shock delivery.
- Structural design and material choices for ruggedization and portability, accommodating storage conditions ranging from backpacks to vehicle glove compartments.



AC MedTech Product Development for De...
TARGETED ENERGY STORAGE & TRANSFER CHALLENGES
Watch on YouTube



Click video to watch a 4-minute synopsis of product engineering challenges and breakthroughs.



SOFTWARE-DRIVEN RHYTHM RECOGNITION & USER EXPERIENCE

Unlike conventional AEDs, which rely on dedicated on-device hardware, Defibrion's solution required real-time heart rhythm analysis via smartphone software. Software solutions required:

- A large source of high-quality electrocardiograms (ECGs) curated into clinically-annotated data to identify life-threatening arrhythmias.
- Skillful development and fine-tuning of a custom algorithm that delivers rapid, accurate ECG analysis.
- A mobile application to guide users quickly through emergency use of the Defibrion AED and administering a defibrillation shock when needed.



Mobile Application Integration

Because traditional AEDs have limited, static visual instructions, the Defibrion AED system was designed to include a smartphone application to significantly improve the user experience. Global digital development partner, **Rightpoint**, tackled key user interface (UI) design requirements:

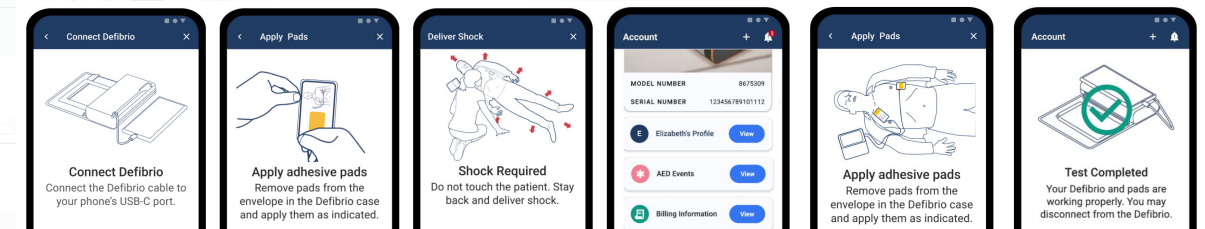
- An intuitive UI that provides a clear step-by-step progression from electrode placement, to heart rhythm analysis, and, when needed, defibrillation.
- Real-time feedback by combining visual and audible cues to significantly improve and transform the experience for first-time users in high-stress situations.
- Streamlined the hardware, firmware, and software interactions, enabling rapid and reliable activation of the AED's energy system.



Developing the Data & Training the Algorithm

Defibrion's AED relies on the rhythm recognition algorithm to accurately process ECG data and rapidly determine shockable rhythms. Training the algorithm to achieve a high degree of accuracy required a progression of software development, including:

- A front-end clinical review tool to enable cardiologists to classify and validate thousands of ECG recordings for algorithm development.
- Real-time analysis of the clinically validated data with layers of software filtering to eliminate the potential of unwanted interferences.
- Algorithm testing against industry benchmarks to ensure high sensitivity and specificity rates required for regulatory compliance.



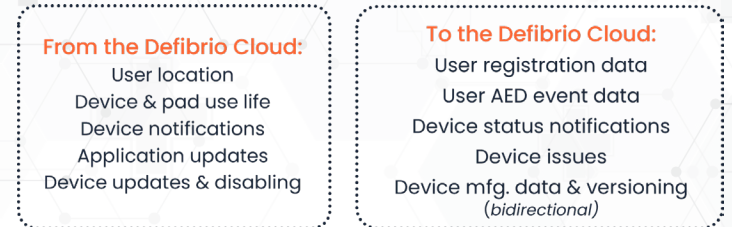
Application screens courtesy of Defibrion.

Secure Cloud Data Integration

To achieve robust and secure data management as well as stringent cybersecurity and privacy requirements, Rightpoint integrated with the cloud data management team.

The Defibrion Cloud enables continuous communication between the device, user app, and cloud server—supporting remote diagnostics, user registration, AED event reporting, device status monitoring, and version-controlled updates.

This bidirectional system ensures devices remain reliable, compliant, and ready to respond when every second counts.



Click video to watch a 3-minute synopsis of software engineering challenges and breakthroughs.





STRATEGIC HARDWARE TESTING TO IMPROVE DESIGN & COMPLIANCE

Developing a life-saving device requires not only advanced engineering but also rigorous testing to ensure real-world durability, reliability, and compliance with regulatory standards. The Hardware Test Engineering team conducted iterative testing cycles to refine Defibrio's design.

Ruggedization & Durability Testing

Defibrio's AED was designed for portability, which inherently meant it had to withstand harsh conditions across multiple environments:

<p>Temperature stress testing simulated extreme heat and cold exposure (e.g., vehicle storage and outdoor use).</p>	<p>Drop, shock, and vibration testing pinpointed structural weaknesses using high-speed imaging and led to reinforcing components.</p>
<p>IP55 ingress testing with custom fixtures verified resistance to both dust and water exposure, ensuring continued functionality in real-world conditions.</p>	<p>Electromagnetic compatibility (EMC) testing confirmed compliance with strict radiated emissions standards, critical for medical device reliability.</p>

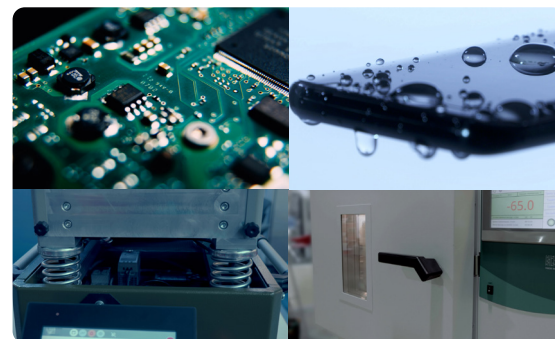


Iterative Testing & Failure Analysis

To ensure reliability in real-world environments, the ruggedization of Defibrio began at a Test Lab directly integrated with the Product Development team. Failure results provided actionable insights that led to design improvements, such as:

- Protection for critical components from high-energy discharge.
- Structural reinforcement techniques to prevent drop-induced damage to internal components.

A rapid, collaborative testing process allowed hardware, firmware, and software teams to iterate in real time, accelerating development while ensuring safety and reliability.



Navigating Regulatory & Compliance Standards

Designed to be a Class III medical device, Defibrio's AED required extensive regulatory test verification for FDA and EU MDR standards and requirements for the UK and Canada. MedTech compliance consultants, **RQMIS**, played a pivotal role in defining the regulatory strategy across all four markets—US, EU, UK, and Canada—establishing clear compliance objectives for both hardware and software development.

With these compliance objectives in place, test engineering developed and executed hundreds of detailed test protocols aligned with global regulatory requirements, ensuring:

- Thorough risk assessment and hazard analysis, guiding design refinements to meet medical safety benchmarks
- Compliance with IEC 60601 standards, validating electrical safety, energy transfer consistency, and patient protection
- Robust documentation for submission, streamlining regulatory approval pathways

Compliance Readiness with Secure Cloud Data

To support regulatory alignment, the team implemented a secure cloud infrastructure that enabled Defibrio to address stringent cybersecurity, data privacy, and operational requirements.

Working closely with regulatory experts, they integrated data security protocols early in development and streamlined documentation workflows—accelerating compliance readiness and supporting successful regulatory submissions.



Click video to watch a 3-minute synopsis of test engineering challenges and breakthroughs.



ENSURING SUPPLY CHAIN RESILIENCE & MANUFACTURING READINESS

De-risking the pathway to production and market readiness, **OnTap Consulting** joined the development effort to assess potential supply chain strains and manufacturing requirements.

Early Supply Chain Integration

To ensure a smooth transition from prototype to production, the team evaluated sourcing risks early, focusing on:

- Securing critical components to prevent delays and shortages.
- Aligning design with manufacturing constraints to avoid late-stage redesigns.
- Developing risk-mitigation strategies to ensure long-term supply stability.

By aligning supplier capabilities with design requirements, the team maintained sourcing stability, minimized lead time risks, and prevented late-stage disruptions that could impact production readiness.



Strategic Contract Manufacturer Selection Process



[READ MORE](#)

Read more in our blog with OnTap Consulting: [Startup Strategy: Avoiding Costly Supply Chain & Manufacturing Setbacks](#).

As the design matured, selecting the right contract manufacturer (CM) was critical to enabling Defibrio's AED to scale for high-volume production without compromising quality, cost efficiency, or regulatory compliance. Efforts focused on:

- Developing a structured Request for Proposal (RFP) to identify the best-fit CM for ramping from prototype builds to production.
- Ensuring the CM aligned with material selection, assembly methods, and production workflows.
- Defining quality control measures and production validation processes to maintain consistency across scaled manufacturing.

By integrating supply chain strategy with scalable production planning, the team minimized production risks and ensured a smooth, de-risked path to manufacturing readiness.



COORDINATING A COLLABORATIVE NETWORK OF PARTNERS

Developing Defibrio's novel, smartphone-powered AED required a highly coordinated network of engineering, regulatory, and manufacturing experts. Among the many contributors, these strategic partners played a pivotal role in creating a comprehensive MedTech product development solution:

 <p>Motiv – A seamless user experience is critical in an emergency, where every second counts. As a leader in product design, Motiv ensured that Defibrio's smartphone-powered AED was intuitive and accessible for non-technical users. Their expertise in ergonomics, usability, and industrial design transformed complex medical technology into a device that can be deployed quickly and confidently in high-stress situations. By optimizing form factor, interaction points, and intuitive handling, Motiv helped create a smartphone-powered AED assembly that is not just effective but instinctive to use when it matters most.</p>	 <p>OnTap Consulting – Scaling a groundbreaking product requires seamless alignment between design and production. OnTap Consulting played a key role in optimizing the supply chain alongside product development, ensuring that sourcing, manufacturing, and logistics kept pace with the evolving technology. By streamlining production planning, OnTap helped create a scalable and efficient pathway to market, enabling Defibrio's smartphone-powered AED to move from concept to reality without bottlenecks or delays.</p>
 <p>Rightpoint – Traditional AEDs are designed for trained responders, often relying on complex audible instructions. Defibrio's smartphone-powered AED needed a radically different approach—one that would guide untrained users through a high-stress emergency with clarity and confidence. Rightpoint tackled this challenge by designing an intuitive mobile interface that simplifies split-second decision-making. Through human factors studies and iterative testing, they refined instructional workflows to reduce hesitation and improve response time for defibrillation. By shifting critical AED functionality into a seamless smartphone experience, Rightpoint's breakthrough in UX design eliminated barriers to adoption, making the device both accessible and empowering for everyday users.</p>	 <p>RQMIS – Providing more than planning, RQMIS delivers end-to-end regulatory execution and continuity across the product lifecycle. From early-stage strategy through post-development operations, they support clients not only in defining regulatory pathways but in navigating them hands-on. For Defibrio, RQMIS architected the quality management system, managed regulatory, quality, and clinical activities, and led communications with authorities across the US, EU, UK, and Canada. Embedded in daily operations, RQMIS continues to manage compliance and cybersecurity requirements, oversee validation logistics, and maintain alignment with global regulatory standards—positioning Defibrio for a successful multi-market launch and sustained regulatory readiness.</p>



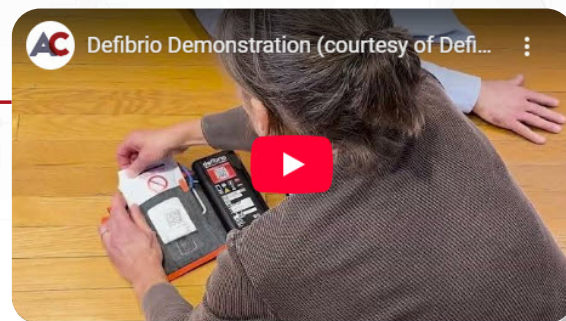
RESULTS | DELIVERING A LIFE-SAVING MEDTECH INNOVATION: THE DEFIBRIO SMARTPHONE-POWERED AED

The development of Defibrio's smartphone-powered AED demonstrates the power of cross-disciplinary engineering, iterative testing, and strategic collaboration in solving complex MedTech challenges, including:

Validated Performance	Regulatory & Production Readiness	Expanded Accessibility & Usability
<ul style="list-style-type: none"> Proven energy transfer system, delivering precise therapeutic shocks. Optimized form factor, balancing ruggedization and portability. Real-time software-driven heart rhythm detection, meeting industry benchmarks. Real-time device monitoring and post-event cloud data storage. 	<ul style="list-style-type: none"> Hundreds of test protocols developed for FDA Class III and EU MDR standards. Supply chain alignment established, supporting scalable production. CM selected for validated quality control and production processes to ensure manufacturing consistency at scale. Regulatory-aligned cloud infrastructure streamlined for compliance and documentation. 	<ul style="list-style-type: none"> Designed for non-expert users, ensuring rapid emergency response. Affordable, portable, and smartphone-integrated, increasing AED accessibility. Defibrio's smartphone-powered AED redefines what's possible in MedTech innovation, broadening access to life-saving technology.



Click video to [watch](#) a demo courtesy of Defibrio LLC



ENGINEER THE IMPOSSIBLE IN HARDTECH

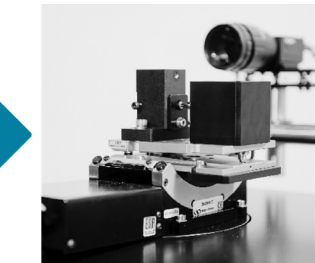
Info@Andrews-Cooper.com
503.565.2000



www.Andrews-Cooper.com



Hardware Product Development



Automation & Robotics



BRING YOUR MEDTECH INNOVATION TO LIFE

Developing complex, regulated MedTech devices demands engineering expertise, strategic partnerships, and a risk-mitigating development framework. At Andrews Cooper, we specialize in turning ambitious ideas into validated, manufacturable solutions.

Ready to transform your vision into reality? [Let's build something groundbreaking—together.](#)