

# Lifesaving Defibrillation Therapy

## UPDATES TO EXISTING DEVICE NEEDED FOR U.S. MARKET ENTRY

### SITUATION

- Manufacturer needed to update its popular combination manual defibrillator device with AED, currently selling in overseas markets, for release in the U.S.
- Market window was closing as the project fell behind schedule due to operational performance gaps

### CHALLENGES

- In-house engineering staff, new to the product, had limited knowledge and understanding of IEC 60601-1 3<sup>rd</sup> Edition requirements
- Unable to identify testing and certification needs, build a test plan, and implement the plan
- Growing backlog of defect fixes, testing, and certification needs were more than the internal team could tackle in a timely, effective manner

### SOLUTION

- MedAcuity provided first-hand knowledge and understanding of IEC 60601-1 3<sup>rd</sup> Edition requirements and how to apply them to the development effort
- Performed debugging and bug fixes, integrated a new tool for code coverage and analysis reporting, and completed a First Article Inspection of the device
- Developed and reviewed test procedures (unit, integration, and regression)

### RESULTS

- Software defect backlog was significantly reduced
- Executed test runs to fully assess updated device and documented results to illustrate compliance
- Updated design documents for design history file
- Updated defibrillator was much closer to satisfying the quality and safety criteria needed for U.S. release

### ABOUT MEDACUITY

MedAcuity is a specialized engineering firm that focuses on medical technology software development. The trusted and experienced firm was founded in 2007 by a team of seasoned software engineers who identified opportunities to fill gaps in the engineering expertise and efficiency facing the medical technology industry. MedAcuity offers extensive experience across the MedTech industry with full life-cycle software development and subspecialties in other areas including tool validation, algorithm development, and cybersecurity.

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