

IEC 62304 and FDA Compliance for ActiGraph Wearable Devices



Challenge:

In order to meet FDA and IEC 62304 software development requirements on their latest activity monitoring devices, the ActiGraph software development team needed a solution that would allow them to automate much of the key activities associated with the testing of its embedded software.

Solution:

After an extensive evaluation process, ActiGraph engineers chose the VectorCAST test automation platform for its advanced functionality and IEC 62304 certification.

Details:

ActiGraph's suite of validated hardware and software products are widely used by prominent scientific, academic, and pharmaceutical organizations worldwide. The company's software platform and wearable devices provide the most comprehensive data analysis and logistics support in the industry. VectorCAST provides ActiGraph engineers with automated test solutions for unit, integration, and system testing, as well as code coverage analysis, requirements traceability, and on-target testing, necessary to help them achieve compliance with FDA and IEC 62304 medical device regulations.

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