



Support for IEC 62304

What is IEC 62304?

IEC 62304 defines a process for ensuring the safety and effectiveness of medical device software. It requires a definition of the intended use of the software, a process demonstrating that the software fulfills those intentions, and a process demonstrating that the software does not cause any unacceptable risks.

The purpose of IEC 62304 is to define the lifecycle requirements for medical device software and to establish a common framework for medical device software lifecycle processes. The lifecycle should be thoroughly described and broken into processes, activities, and tasks. The standard enhances the reliability and safety of software by requiring detail and rigor in design, test, and verification.

IEC 62304 tackles software architecture design in chapter 5, the Software Development Process (§5.3.1 - §5.3.5). The standard defines architecture as describing software structure and identifying software items. Architecture design also describes interfaces for software items.

Software Architecture verification is discussed in §5.3.6 where it states that you must verify and document that the architecture implements the system and software requirements, including risk control. The architecture supports interfaces between software and hardware and supports proper operation of off-the-shelf software.

How Lattix products support IEC 62304

IEC 62304 demands a process that performs risk and architecture analysis. Some companies document this process with text documents. Lattix can simplify and automate this process by providing an actual picture of the software architecture and providing the metrics that are required for IEC 62304 compliance.

Further, Lattix can be used during the build/continuous integration process to keep the desired architecture in line with the design rules. §5.3 and §5.4 can be fulfilled easily with the Dependency

Structure Matrix (DSM) and Conceptual Architecture Design (CAD) views generated by Lattix Architect. These views can be exported as needed for documentation.

In addition to software and firmware architecture analysis, Lattix Architect can be used to save time in scheduling unit and verification testing by producing an impact analysis report showing the changed items in a build. This allows you to know if a code change impacts a feature or function and therefore the tests corresponding to that feature or function need to be run again. This can be done much more quickly and with far less cost than the typical solution, usually a team meeting with all the interested parties going over code changes. Lattix will also educate you on code and interfaces with third party libraries, adding to the value of the software quality score.

How Lattix Architect can be utilized for IEC 62304

- Compose software into units
 - Do the software components the engineer describes in their documentation exist in the code? The DSM and CAD views can verify this
- Analyze software architecture relative to safety risk impact
 - Lattix can assess coupling that may cause problems or unwanted side effects and assess change impact in relation to risk analysis
- Aid Development in adhering to the intended architecture (Design Rules)
- Aid Quality in verifying statements of change and impact performed on software packages
- Provide metrics on complexity, cyclicity, and stability

Try Lattix Architect on your IEC 62304 project

Contact Lattix at sales@lattix.com or call 978-664-5050.

Find us at www.lattix.com.

Understand, Define, and Control Software Architecture