Software is a part of our lives. Embedded into everyday equipment, into living and working environments or modern means of transportation, countless processors and controllers make our lives simpler, safer, and more pleasant. We help organizations to develop software systems that are dependable in every aspect, and empirically validate the necessary processes, methods, and techniques, emphasizing engineering-style principles such as measurability and transparency.

The Fraunhofer Institute for Experimental Software Engineering ISE in Kaiserslautern has been one of the world’s leading research institutes in the area of software and systems engineering for more than 20 years. Its researchers have contributed their expertise in the areas of Processes, Architecture, Security, Safety, Requirements Engineering, and User Experience in more than 1,200 projects.

Under the leadership of Prof. Peter Liggesmeyer, Fraunhofer ISE is working on innovative topics related to digital ecosystems, such as Industrie 4.0, Big Data, and Cyber-Security. As a technology and innovation partner for the digital transformation in the areas of Autonomous & Cyber-Physical Systems and Digital Services, the institute’s research focuses on the interaction between embedded systems and information systems in digital ecosystems.

Fraunhofer ISE is one of 72 institutes and research units of the Fraunhofer-Gesellschaft. Together they have a major impact on shaping applied research in Europe and contribute to Germany’s competitiveness in international markets.

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**SOFTWARE-BASED SYSTEMS FOR HEALTH AND QUALITY OF LIFE**

In Health Care, too, software allows increases in efficiency and effectiveness, such as better diagnostics and treatment or the optimization of medical and administrative processes in health care institutions.

There is hardly any other area of our daily lives where computer technology is so close to humans, and consequently, mistakes can have very serious effects. Reliability, security and safety, and data protection are essential for these systems.

Our software and systems engineering approach supports you all the way from the elicitation of requirements to validation. Together with our customers, we develop innovative solutions for software development that efficiently fulfill the requirements of IEC 62304, DIN EN 60601-1-4, and ISO 12207 for medical devices, and provide assistance in systematically implementing them in daily practice. We integrate future-oriented methods and techniques that ensure quality requirements (e.g., in accordance with ISO/IEC25000) efficiently and economically. Safety and security are the top priorities in this respect. We use new methods to support you in performing risk management according to ISO 14971 for software, and to use techniques such as Failure Mode and Effects Analyses (FMEA) and Fault Tree Analyses (FTA) for analyzing software safety. Custom-tailored quality management approaches (e.g., similar to ISO 13485) are defined as supporting processes.

Fraunhofer IESE provides support to all stakeholders in the health care sector when it comes to developing and testing software-based innovations, including, in particular, interconnections between devices and services. The institute assists its customers in developing complex information systems as well as in implementing domain-specific requirements, such as those of ISO 80001.

**Customer Benefits:**
- Higher safety of the software and thus of the medical services
- More efficient development and faster time to market
- Reduction of development and quality assurance costs
- Provable safety and quality requirements
- Provable process and product quality

**COMPETENCE IN SOFTWARE AND SYSTEMS ENGINEERING**

Fraunhofer IESE provides support for manufacturers and users of software and medical devices in the health care sector during all phases of software and systems development.

**SOFTWARE DEVELOPMENT**

**Requirements Management**

We support you in eliciting requirements and in developing suitable requirements specifications as well as in managing the requirements.

**Usability Engineering and User Experience**

With our expertise, we support you in ensuring that usability is considered during development, and in integrating it into the software and systems lifecycle (IAW EN 60601-1-4 and 62366).

**System and Software Architectures**

The specification and implementation of future-oriented architectures is one of our core competencies. This also includes the evaluation and re-structuring of your existing software architecture, taking into account special constraints such as runtime behavior or memory requirements.

**Software Product Lines and Reuse**

We support you in defining and introducing the idea of software product lines, and in defining suitable and safe reuse concepts.

**SOFTWARE QUALITY MANAGEMENT**

**Risk Management**

The team of Fraunhofer IESE supports you in the standard-compliant implementation of ISO 14971 requirements by defining and implementing a risk management process for software that is adapted to your context and the corresponding documentation.

**Safety Analyses**

We help you to select and use adapted techniques such as FMEA, FTA, or introduce modern processes such as component fault trees in your organization.

**Development Processes**

We support you in the standard-compliant definition (e.g., IEC 62304, ISO 12207, V-Modell), structuring, documentation, and implementation of development processes and in the selection of methods, tools, and techniques that are suitable for passing certification procedures.

**Static Quality Checking Techniques**

Together with you, we define appropriate and innovative processes for verification in parallel to development.

**Model-based Testing and Test Automation**

We support you in the design and introduction of model-based testing techniques for embedded software, focusing in particular on test automation aspects.

**Quality Management**

We support you in defining, structuring, and establishing a standard-compliant quality management system for your software development in the style of standards such as ISO 9000-3 or ISO 13485, or the FDA Quality System.

**Software Measurement Systems**

Through the use of defined metrics, which we derive in a systematic manner adapted to your demands, quality aspects can be expressed in concrete statements.