SOFTWARE DEVELOPMENT FOR ENDOSCOPIC INVESTIGATION: PROBLEMS AND BASIC APPROACHES

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Introduction

The purpose of author's cooperative project is the development of technology for non-invasive endoscopic investigation, using the experience and achievements in sensors research for hyper spectral analysis and modern endoscopic equipment. The developed method for experimental endoscopic hyper spectral investigation was discussed earlier. Let's admit, that proposed methodology allows to study the physical displays of anomalous formations on the stomach's internal surface and to accumulate the actual data for an objective analysis by means of the mathematical methods for different quantitative estimation. As a result, presented method for endoscopic investigation requires the development of specific software.

Problem statement

It is common knowledge that improper work of the software can have unforeseeable consequences, which are related to the state of human health. Therefore the definition of well-known facts about medical systems and equipment failures all over the world is discussed, e.g.: two people died in incident involving heart pacemakers because of software errors; an infusion pump delivered the maximum rate instead of intended rate subsequent entering certain valid data because of a software error; an artificial intelligence medical system provided the wrong advice, leading to a drug overdose; a multiple-patient monitoring system failed to store collected data with the correct patient due to a software fault.

It is necessary to admit the importance of software quality and reliability in minimally invasive surgery, especially in accordance to its fast development. Minimally invasive surgical procedures avoid open invasive surgery in favor of closed or local surgery with fewer traumas. These procedures involve use of laparoscopic devices and remote-control manipulation of instruments with indirect observation of the surgical field through an endoscope or similar device, and are carried out through the skin or through a body cavity or anatomical opening.

Special medical equipment may be used, such as: fiber optic cables; miniature video cameras; special surgical instruments handled via tubes inserted into the body through small openings in its surface. The images of the interior of the body are transmitted to an external video monitor and the surgeon has the possibility of making a diagnosis, visually identifying internal features and acting surgically on them. However, the safety and effectiveness of each procedure must be demonstrated with randomized controlled trials.

Thus, **actual problem** consists in not only creation of new medical software, but in the creation of the medical system with required quality, reliability and safety. Let's discuss main definitions in accordance to international standards, and let's formulate typical design methods of software engineering for providing essential level of quality, reliability and safety.

Medical software engineering for life-critical systems is particularly difficult, partly because of main software defects mostly appeared on the specification phase. After all phases of the software development these early injected defects will cause the serious software faults. That's why, it is essential to discuss the *basic approaches for providing of required level of medical software's quality*.

- First approach is to carefully code, inspect, document, test, verify and analyze the system.
- Second approach is to certify a production system, a compiler, and then generate the system's code from specifications.
- Third approach uses formal methods to generate proofs that the code meets requirements.

The *estimation of software reliability for medical diagnostic systems* based on modern approaches and techniques can be considered through:

- Inspection methods which assume verification of software in accordance to the normative document's requirements by the analysis of documentation and development processes;
- Use of the specific metrics which allow to evaluate the level of software quality and reliability based on probability measured analysis of software behaviors;
- Application of mathematical models for the estimation of probabilistic indexes of the reliability.

Medical software safety is a conservation of human life and its effectiveness and the prevention of damage to items as per operational requirements. Hence, risks of medical sort are usually managed with the methods and tools of safety engineering. *Typical design methods* include: the probabilistic risk assessment; the method that combines failure modes and effects analyses with fault tree analysis.

All presented approaches improve the software quality in safety-critical systems by testing or eliminating manual steps in the development process, because people make mistakes, and these mistakes are the most common cause of potential life-threatening errors.

Conclusions

Consequently, the support of required medical system's quality, reliability and safety, especial during software development for endoscopic investigation, is essential and can be provided with contemporary methods and tools of medical software quality, reliability and safety engineering.

The conception of providing the quality, reliability and safety of the medical systems consists of:

- Evaluation of system quality, reliability and safety on all stages of software life cycle;
- Realization of specific tools for estimation of the software reliability and quality;
- Application of the modern progressive techniques during software development and testing, for example Test Driven Development (TDD).