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MEDICAL SYSTEMS: QUALITY AND SAFETY IN ROBOTIC SURGERY

A *life-critical system* or *safety-critical system* is a system whose failure or malfunction may result in: death or serious injury to people or loss or severe damage to equipment or environmental harm. Medical systems are instantly related to the critical systems. Therefore the definition of well-known facts about medical systems and equipment failures is discussed [1].

Medical software engineering for life-critical systems is particularly difficult. Hence, risks of medical sort are usually managed with the methods and tools of safety engineering. Typical design methods include probabilistic risk assessment, a method that combines failure modes and effects analysis with fault tree analysis [2].

Also it is essential to discuss the basic approaches for providing of required level of medical software's quality. The 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. All of these approaches improve the software quality in safety-critical systems by testing or eliminating manual steps in the development process [3], because people make mistakes, and these mistakes are the most common cause of potential life-threatening errors. All above mentioned approaches are devoted to increase the quality and safety of medical systems, e.g. in *intensive care* (which deals with healing patients), and also *life support* (which is for stabilizing patients), such as: heart-lung machines, mechanical ventilation systems, infusion pumps and insulin pumps, radiation therapy machines, robotic surgery machines [4].

Consequently, it is necessary to admit the importance of software-quality in *robotic surgery*, especially in accordance to its fast development. Three major advances aided by surgical robots have been remote surgery, minimally invasive surgery and unmanned surgery. Major potential advantages of robotic surgery are precision and miniaturization. Further advantages are articulation beyond normal manipulation and three-dimensional magnification.

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 [4]. Special medical equipment may be used, such as fiber optic cables, miniature video cameras and 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.

As a result, the support of required medical system's quality and safety, especial in robotic surgery, is essential and can be provided with contemporary methods and tools of medical software safety engineering that are discussed previously.

References

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