Data-driven analysis of user interface software in medical devices

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User interface software in medical devices provides functionalities necessary for smooth and safe use of the device in clinical workflows. In advanced systems such as robotic-assisted surgery, user interface functions can be highly sophisticated, e.g., involve the detection and translation of a doctor's hands movements into micro-movements of robotic arms, allowing doctors to perform complex surgeries that were not possible before.

Developing sophisticated software with zero defects is a notoriously hard problem. In the medical domain the problem is particularly delicate, as software defects can ultimately result in patient harm. Recent estimates on incidents with medical devices indicate an escalating trend, with software defects being constantly one of the top causes of incidents since 2016, and accounting for 22.7% of medical device recalls in the first quarter of 2018. To date, several studies have been carried out providing an aggregate view of software defects in medical devices. A detailed analysis of the nature and impact of user interface software defects has not been performed yet. Such detailed analysis would bring powerful insights that can be used by developers to better understand latent software defects and identify them in advance, before incidents happen.

In this talk, I will present a study conducted in collaboration with the US Food and Drug Administration that aims to quantify and classify user interface software defects in the current generation of medical devices. The study involved a systematic and detailed analysis of nearly 8,000 medical devices recall records published by the FDA from September 2012 to August 2015. A medical device recall is a corrective action initiated by the manufacturer to fix critical defects in a device already in the market. Each recall record includes a semi-structured description of the reason for the recall and the corrective action performed by the manufacturer. I will discuss the analyzed dataset, including the analysis method, the challenges faced while performing the analysis, the results obtained, and the opportunities for improvement.

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