ERF Workshop on Medico-surgical-rehab robots: fostering community interaction for safety, standards & regulatory issues

Talk Title: Integrating Safety in the Designing Process for Healthcare Robotic Systems

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Abstract

Due to the rise of the world population's life expectancy and the increased pressure to health service providers, there is a need of adopting novel technologies for intervention and rehabilitation robotic systems faster. Although there is a great number of excellent ideas developed, they find it difficult to reach the market, with the most common reason being safety and as a result inability to obtain certification. The issue is that healthcare robotic systems need to follow the "classic" route of certification for medical-related equipment, i.e. extensive trials for a prolonged duration of time, with tools that are developed to assess risk for a different era of engineering.

These barriers have a financial and a technological dimension. From the financial perspective the cost of getting certification is prohibitive for smaller pioneer companies/institutions. From the technological perspective, the certification process currently available is based on risk analysis tools that are effective in identifying direct relationships between causes and faults in components, but often indirect dependencies may not be easily recognized. Moreover, the majority of modern healthcare systems are cognitively intense applications with the decision making being shared with the operator and the notion of "human error" is very narrow to describe safety issues. This is also important given the fact a lot of robotic systems utilise adaptive behaviour to improve performance.

The only way to move forward in bringing new technologies is to ensure safety by changes on the framework of development but also on the regulatory level, i.e. what is really a safe/unsafe situation? This presentation aims in discussing the direction the changes we need to do in developing and certifying healthcare robotic systems. For the technological dimension we need to put safety in the core of the design process. This requires a rethinking of how we develop healthcare robotic system under "unknown" conditions like the extended interaction with a human and adaptive behaviour. For this we will need to find new ways that will validate, and verify these systems not on a cause-and-effect basis but more on a context basis.

What are the key changes we need for regulations?

- Change methods from reliability to systems engineering?
- Change evaluation focus from trial to design?
- Change focus of the trials from the components to the system, especially the interaction with the operator?