New Medical Robotics Standards – Aiming for Autonomous Systems

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***Abstract*—Autonomy is a fundamental attribute of robotics, yet it is one of the hardest terms to define, assess and regulate. Autonomy probably poses the greatest safety challenge within the medical field. AI methods and decision support systems are playing an increasing role in all domains of healthcare, and their breakthrough in medical robotics is just around the corner, assuming a safe regulatory framework can be developed. Supporting these trends, a new generation of robotics standards is emerging both in the IEEE and in the ISO/IEC domain, already focusing on the big challenge of the future medical systems: autonomy. This work provides a brief overview of the brand new standards targeting this complex area.**

I. New robotic standards

The importance of standardization had become paramount in the medical domain, since that is believed to be the best way to increase safety systematically. Harmonized global standards and regulatory frameworks are offering ways to product certification through standardized testing requirements and protocols [1]. However, until very recently, a huge gap existed, since the traditional robotics standards excluded service robots and medical robots, particularly. In the past 7 years, a joint working group of robotic experts was addressing this problem, and this year, the very first ISO/IEC joint Technical Report (TR) on the problem of autonomy for medical electrical systems (MES) (including robots) appeared [2]. This is a first step towards the standardized assessment of robot capabilities, primarily focusing on their autonomous functions, while practical guidelines on methods for robot categorization and certification are also on the horizon.

A. MES with a Degree of Autonomy (DoA)

The new TR offers an unambiguous solution to describe and assess the autonomous capabilities of an MES. Relying on some earlier work in the field of industrial automation and service robotics [3], the TR recommends the parametrization of DoA along four cognition-related functions of a system, which are affecting capabilities of an MES to *Generate*, *Execute*, *Monitor* and *Select* an option related to a robot task. Each of these functions can be driven by a human or a computed (or mixed under some conditions), which would then lead to the objective assessment of the DoA of the full system. DoA can vary from low to high, with zero meaning "no autonomy", and the other end of the scale meaning a "full autonomy" system. DoA can be classified at different granularity levels, depending on where and how the above safety functions are implemented.

B. Basic safety & essential performance for surgical robots

The IEC TC 62/SC 62D joint committee worked to provide a practical degree of safety for surgical robots, resulting in a brand new standard to be published later this year [4]. It defines the basic types of surgical robots and tools, and identifies integrated components. The standard collects all relevant mechanical and thermal hazards, along with the fault conditions of the equipment and the required usability trials.

C. Basic safety & essential performance of rehab robots

Another particular standard coming from the same group addresses the hazards associated with the loss of Situation Awareness (SA) in rehabilitation robotics [5]. This may be critical when a human operator is needed to supervise a task, or interact with a robot to reduce risk. According to the new standard, the manufacturers will have to include fundamental information about the testing and SA for their upcoming robotic systems.

II. Ethical aspects of robotics

Human medicine has changed a lot recently due to ICT, with much bias against robotic systems. Elevating it to the regulatory level, the EU is working on a robot ethics doctrine [6], and also, the IEEE is drafting relevant standards (*IEEE P7000 - Model Process for Addressing Ethical Concerns During System Design*, *IEEE P7001 - Transparency of Autonomous Systems* and *IEEE P7007 - Ontological Standard for Ethically Driven Robotics and Automation Systems*). From the user's (and the manufacturer's) point of view, safety is the single most important feature of any surgical devices. The community strongly believes that future standards should focus more on patient safety and treatment improvement rather than pure technical metrics, and will continue to work towards that goal.

References

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