Doctoral Dissertation
Doctoral Program in Metrology (36^{th} cycle)

Applied Metrology for the Digital Transition in Healthcare

A metrological approach to the development of assistive solution for *Health 4.0*

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Abstract

This doctoral thesis discusses the design and implementation of a series of assistive solutions developed in the context of the digital transformation of the healthcare sector. Digital transformation in healthcare represents a highly relevant topic in the current socio-healthcare context. This process involves the adoption and integration of the enabling technologies derived from the fourth industrial revolution to improve the efficiency, accessibility, and quality of healthcare services. For this reason, it is often referred to as *Health 4.0*. Among the main challenges addressed are the digitalization of clinical data, the implementation of telemedicine systems, the use of Artificial Intelligence for medical data analysis, the enhancement of clinical treatments, and the security of healthcare information.

In the era of Health 4.0, where digital technologies revolutionize healthcare, metrology is pivotal. As a matter of fact, the integration of metrology with Health 4.0 technologies, including Artificial Intelligence (AI), Internet of Things (IoT), and Augmented Reality (AR), enhances precision in measurements, ensures data accuracy, and contributes to the reliability of advanced healthcare systems. It provides a foundational framework for calibration, quality assurance, and standardized measurements, fostering the seamless convergence of digital innovations in healthcare.

Going into the details of this work, the first Chapter briefly provides a historical overview of the four industrial revolutions that have marked the past centuries. Subsequently, particular attention is devoted to the introduction of enabling technologies of the *4.0* paradigm, such as Augmented Reality, Artificial Intelligence, and the Internet of Things. The Chapter concludes by explaining how the principles underlying the fourth industrial revolution can also be applied in other contexts, including healthcare, demonstrating new declinations and their respective benefits with respect to traditional practices.

Subsequently, this doctoral thesis elucidates the aforementioned assistive solutions. Chapter 2 focuses on the development of Brain-Computer Interfaces based on Steady-State Visually Evoked Potentials induced through Augmented Reality technology, aiming to create highly wearable and portable systems not confined to laboratory settings. In a nutshell, Brain-Computer Interfaces are an integration of hardware and software

systems that establish a direct communication path between users and external devices. After a metrological analysis of the performance of the developed systems, two illustrative application scenarios are briefly presented, demonstrating the efficacy and potential of such systems. The first scenario delineates a hands-free interaction mode within an operating room by the medical team. This mode facilitates the monitoring of both the patient and their health status through augmented reality visualization of vital parameters. The second scenario highlights an innovative therapy approach for school-age patients with attention or learning disorders. In both cases, the developed system exhibits capabilities that surpass traditional systems.

Chapter 3 describes the development of a patient monitoring system in the operating room based on Augmented Reality. Traditionally, the medical team is divided between monitoring the patient's vital parameters displayed on the electromedical instrumentation monitors and those who directly operate on the patient. Sometimes, the shortage of medical staff necessitates performing both tasks, occasionally risking distraction and an inability to respond promptly in case of deteriorating patient health conditions. For this reason, the developed system aims to display the patient's vital parameters in real-time through augmented reality to the medical team, ensuring that the operators do not lose sight of the patient and can act promptly in case of danger. In this case as well, a metrological characterization of the system has enabled an understanding of its performance in terms of communication accuracy and latency, demonstrating how such a system can be effective and efficient compared to traditional practices.

Chapter 4, finally, describes the development of two clinical decision support systems. In brief, a decision support system is a system that, based on collected data, provides real-time objective information to the medical specialist. Systems of this kind find application especially in contexts where decisions are made based on the experience of the medical specialist. In this thesis work, two systems are presented.
The first system concerns the evaluation of the effectiveness of scoliosis braces. Specifically, the system is based on the acquisition and processing of thermal images of the patients' backs collected through infrared thermography instrumentation. The temperature difference measured between different areas of the patient's back is caused by the varying pressure exerted by the brace in different back zones. The system can provide a statistically-based result regarding the correctness of the applied pressure and, therefore, the effectiveness of the brace, thus avoiding frequent X-ray prescriptions, which can be harmful to the patient.
The second system, on the other hand, relates to the assessment of perfusion quality in the field of laparoscopic surgery: following an intervention in the intestinal tract, it is crucial to know the quality of perfusion to determine whether it is necessary to intervene again on the patient or not. The proposed system takes input from the video streaming from the endoscope that analyzes the relevant intestinal tract. Subsequently, image processing allows for a statistical understanding of perfusion quality, providing the physician with objective support, especially in cases where making a decision through simple visual inspection, as traditionally done, is challenging.

All the systems presented have been meticulously designed and developed, taking into consideration the stringent requirements of the healthcare sector. For this reason, appropriate metrological characterizations of the functional components have been conducted to assess the performance of the systems in anticipation of their future utilization in everyday healthcare practices.