Verification and Validation of Medical Cyber–Physical Systems

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INTRODUCTION

In recent years, the health care services have followed the evolution of Information and Communication Technologies (ICTs). Telemedicine has been using ICTs, such as computers, internet and smart phones, to overcome geographical barriers and expand access of these services to remote areas and areas that need to improve the quality of care to the population. The idea of Telemedicine is to provide Electronic Health Records (EHR) on an individual and to allow the exchange of such information between health-care professionals for distance clinical support (WHO, 2010).

To make these applications possible it is necessary to integrate computation with physical processes, yielding a class of systems called *Cyber-Physical Systems* (CPS). Helen Gill, from the *National Science Foundation* (NSF) - U.S., was the researcher responsible for coining the term CPS in 2006, claiming the need for understanding the joint dynamics of the components of these systems, such as computers, software, networks, and physical processes. In CPS, feedback loops between physical processes and computing occur. Likewise, computing interferes in physical processes (LEE and SESHIA, 2011).

In this context, some trends and challenges are related to modeling and control of hybrid systems, networks of sensors and actuators, computational abstraction and architectures of these systems (PARK, ZHENG and LIU, 2012). All these factors relate to the mode of dealing with intrinsic aspects of systems focused on physical processes, such as the diversity and amount of information to be captured and processed, the heterogeneity of the elements interacting and the simultaneity of events occurring.

With the increasing elderly population and the high costs associated with quality of life, health has become one of the main application domains of a CPS, these applications are named *Medical Cyber-Physical Systems* - MCPS (LEE et al., 2012). As a distinct class of CPS, MCPS introduces additional computational entities to help the caregivers in the decision support regarding the control of the health of patients. In these systems, the data acquired by monitoring devices are analyzed to determine the condition of the patient and to provide information about the current situation to the experts. Moreover, the most appropriate treatment can be automated by means of actuator devices connected directly to the subject.

The main concern of an MCPS is to ensure patient safety, and therefore its development is considered complex because of insufficient understanding of the dynamics of the human body in response to any treatment. Thus, it is essential to verify if the developed system maintains compliance with its specification as well as to validate that its features meet the needs of professionals who will make use of MCPS.

The aim of this chapter is to provide the tools and approaches currently adopted in the MCPS Verification and Validation (V&V), in order to discuss the state-of-the-art related to this research challenge. In this way, we will provide a survey that will identify and compare proposed solutions regarding different aspects such as contribution, formalisms, tool support and testing procedures for these systems. In addition, we will present the systematic review process used in this research.

BACKGROUND

In this section, we introduce the fundamental concepts and main approaches applied to MCPS testing, such as V&V activities and Model-Based Testing (MBT). In addition, we will present some related works.

Verification and Validation Activities

Software verification and validation is an important stage of the system development life cycle. It is intended to show that a system both conforms to its specification and that it meets the expectation of the system customer (SOMMERVILLE, 2011).

Verification and validation are activities that complement each other to achieve a common purpose, which is to ensure that the system must be good enough for its intended use. Verification is concerned to checking if the developer is building the product right. Validation, however, aims to evaluate if the developer is building the right product.

The main activity of V&V process is system testing. In accordance with Utting and Legeard (2007) "Testing is an activity performed for evaluating product quality and for improving it, by identifying defects and problems". Summarizing, *Testing* means to execute a system in order to detect *undesirable behaviors* (failures).

With the advent of model-based development approaches, artifacts and the models themselves, the properties formalized and results of verification and tests may be used as evidence of the MCPS quality (LEE et al., 2012). In MCPS, the patient safety is the main concern. Hence, these systems must be completely tested.

Model-Based Testing

The *Model-Based Testing (MBT)* term have been constantly adopted to describe a variety of techniques used to generate tests (UTTING and LEGEARD, 2007). The four main approaches known in this group are: *1)* generation of test input data from a domain model; *2)* generation of test cases from an environment model; *3)* generation of test cases with information about their outputs (oracles) from a behavior model; and, *4)* generation of test scripts from abstract tests.

Since each clinical scenario of an MCPS encompasses a heterogeneity of medical devices, all controlled by computer systems to support decision making, often with automated interventions, the safety patient must be assured by the system. Thus, it becomes essential that MCPS developers make use of the approaches and tools more adequate to verify and validate such systems. Hence, this is the motivation to perform this research.

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