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Demo Abstract: A Platform for Implantable Medical Device Validation

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ABSTRACT

Designing bug-free medical device software is difficult, especially in complex implantable devices that may be used in unanticipated contexts. In the 20-year period from 1985 to 2005, the US Food and Drug Administration's (FDA) Maude database records almost 30,000 deaths and almost 600,000 injuries from device failures [8]. There is currently no formal methodology or open experimental platform to validate and verify the correct operation of medical device software. To this effect, a real-time Virtual Heart Model (VHM) has been developed to model the electrophysiological operation of the functioning (i.e. during normal sinus rhythm) and malfunctioning (i.e. during arrhythmia) heart. We present a methodology to extract timing properties of the heart to construct a timed-automata model. The platform exposes functional and formal interfaces for validation and verification of implantable cardiac devices. We demonstrate the VHM is capable of generating clinically-relevant response to intrinsic (i.e. premature stimuli) and external (i.e. artificial pacemaker) signals for a variety of common arrhythmias. By connecting the VHM with a pacemaker model, we are able to pace and synchronize the heart during the onset of irregular heart rhythms. The VHM has been implemented on a hardware platform for closed-loop experimentation with existing and virtual medical devices. The VHM allows for exploratory electrophysiology studies for physicians to evaluate their diagnosis and determine the appropriate device therapy. This integrated functional and formal device design approach will potentially help expedite medical device certification for safer operation.

Categories and Subject Descriptors

C.4 [**Performance of Systems**]: Reliability; D.2 [**Software Engineering**]: D.2.4 Software/Program Verification

General Terms

Reliability, Verification, Experimentation

Keywords

Real-time systems, medical devices, validation, cyber-physical systems

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1. INTRODUCTION

Safety recalls of pacemakers and implantable cardioverter defibrillators due to firmware problems between 1990 and 2000 affected over 200,000 devices, comprising 41% of the devices recalled and are increasing in frequency [7]. There is currently no formal methodology or open experimental platform to validate and verify the correct operation of medical device software. The FDA has expressed the need for rigorous real-time methodologies to validate and verify medical device software as is currently done in the domains of avionics and industrial control automation [6].

We aim to demonstrate our initial efforts to model a part of the human physiology (i.e. the heart) with timed automata and interface it with real and virtual medical devices to validate and verify the software in the medical device. We choose the human heart as it has one specific function and the efficacy of heart rhythm management devices may be observed in relatively unambiguous electrogram (EGM), surface electrocardiogram (ECG) and timing signals. A primary goal of this demonstration is to illustrate the need for integrated functional and formal modeling of the medical device with closed-loop interaction with a validated physical model. We demonstrate this through the development of a Matlab/Simulink model and an implementation in real hardware.

Medical devices are inherently Cyber-Physical Systems where the control and computation within the device is tightly coupled with the sensing and actuation of the biological physical substrate (e.g. the heart). It is therefore essential to model the functioning of the device within the physical environment. The relation between the physical state and the device state is largely non-deterministic, interactive and cannot be fully captured by computation models. The mod-

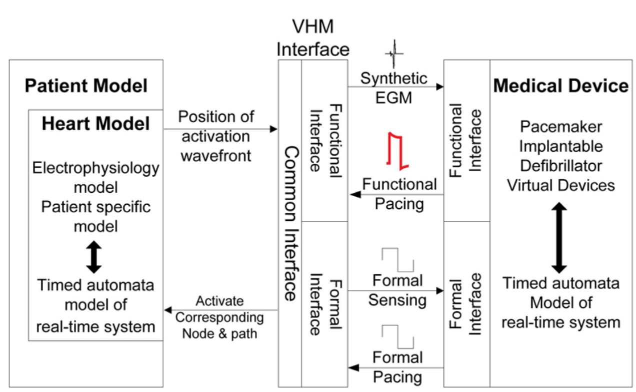

Figure 1: Structure of the heart model platform

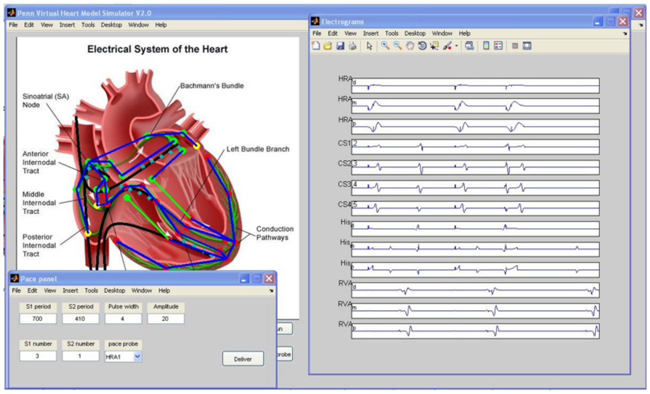

Figure 2: Heart Model interactive screen with electrograms and pacing panel

eling of the physical substrate must therefore be restricted to specific cases and conditions of operation. Thus, the validation and verification observations are only valid for those specific cases.

To address this need, a Virtual Heart Model (VHM) has been developed to emulate the heart's electrophysiological operation for specific common arrhythmias. The VHM exposes functional and formal interfaces for validation and verification of implantable cardiac devices, as shown in Fig. 1. In this investigation, we present a methodology to extract timing properties of the heart to construct a timed-automata model. The functional model is then validated by comparing the behavior of the VHM to three common cases of normal and abnormal heart rhythm. These cases are observed in real patients due to failure of impulse generation and failure of impulse propagation. The clinical relevance of the electrogram outputs from the model have been validated for these specific cases by an electrophysiologist.

Now that the VHM has been validated, we are in the position to validate and verify medical devices in closed-loop operation with the VHM. We designed and validated the functional pacemaker model for the two most frequent arrhythmias. The formal model of the pacemaker was designed and verified within the context of the VHM using Simulink Design Verifier [2]. Following this, an initial version of the VHM was implemented on a FPGA-based hardware platform and the pacemaker was implemented on a microcontroller-based platform for closed-loop experimental evaluation.

The primary contribution of this effort is the development of an integrated functional and formal device design approach which has the potential to help expedite medical device certification for safer operation. In addition, the VHM allows for exploratory electrophysiology studies for physicians to evaluate their diagnosis and determine the appropriate device therapy.

2. MEDICAL DEVICE EVALUATION

The Virtual Heart Model (VHM) was implemented on Xilinx Spartan-3, XC3S1000 FPGA [3]. The timed automata models for the heart model and pacemaker were designed to work with a 10MHz clock. The transition from Simulink and Stateflow design to VHDL description was done manually although appropriate tools exist, which can automatically extract VHDL code from Stateflow design ([4], [5]). Since manual migration from Simulink to VHDL can be a cause of discrepancy between two designs, the use of automatic translators should be a part of future VHM models.

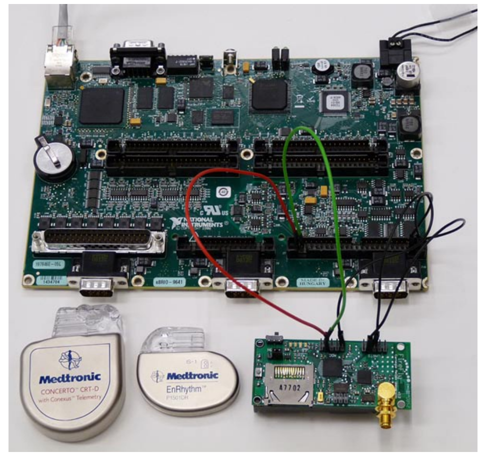

Figure 3: Closed-loop experimental setup with hear model on the FPGA board and pacemaker implemented on the FIreFly sensor node. Medtronic cardiac defibrillator and pacemaker models are shown for reference.

In order to demonstrate how the VHM model can be used for closed-loop black-box testing of implantable medical devices, we used a setup shown in Fig. 3. The pacemaker design described in previous section was implemented on FireFly sensor nodes [9]. FireFly is a low cost, low-power, platform based on the Atmel ATmega1281 8-bit micro-controller with 8KB of RAM and 128KB of ROM. The nodes run the nano-RK [1], real-time operating system developed with timeliness as a first-class concern. nano-RK is a fully preemptive RTOS that satisfies the need for timing precision, priority scheduling and fine-grained resource management. On FireFlies, nano-RK operates with a 1ms OS tick. The pacemaker was implemented on a FireFly node using five tasks for atrial and ventricle sensing and pacing. Each task was assigned a period of 10ms. This implementation, while not fully reflective of the complexity of a modern pacemaker, is simple and allows the evaluator to easily disable some of the tasks to test pacemakers in any of the modes. In our initial implementation, we have been able to experimentally validate the closed loop behavior of the system.

3. REFERENCES

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