

Automated Verification of Quantitative Properties of Cardiac Pacemaker Software*

Marta Kwiatkowska and Alexandru Mereacre

Department of Computer Science, University of Oxford, UK
{marta.kwiatkowska,mereacre}@cs.ox.ac.uk

Abstract

This poster paper reports on a model-based framework for software quality assurance for cardiac pacemakers developed in Simulink and described in [3]. A novel hybrid heart model is proposed that is suitable for quantitative verification of pacemakers. The heart model is formulated at the level of cardiac cells, can be adapted to patient data, and incorporates stochasticity. We validate the model by demonstrating that its composition with a pacemaker model can be used to check safety properties by means of approximate probabilistic verification.

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1 Introduction

Today's implantable medical devices are increasingly often controlled by embedded software and rigorous software design methodologies are needed to ensure their safe operation and to avoid costly device recalls. The natural models for medical devices, such as cardiac pacemakers [6], GPCA infusion pumps [8] and continuous glucose monitors [11], are stochastic hybrid systems: they involve discrete mode switching and nonlinear continuous flows, e.g., electrical signal or glucose level, while at the same time allowing for stochasticity that arises from randomness of the timing of events. Therefore, developing effective methodologies to provide safety assurance in this setting by means of *quantitative verification* is an important challenge.

Regarding cardiac pacemakers, a number of model-based frameworks have been proposed, to mention the Virtual Heart Model (VHM) of Jiang *et al.* [5, 7]. Though mainly intended for simulation and testing, its timed automata pacemaker model [6] has been verified using UPPAAL [10] against a *random heart model*. The random heart model can capture the timing delays between events, but is unable to model the stochasticity in the timing that is characteristic in a heart rhythm and varies from patient to patient. Following a suggestion in [6] that physiologically-relevant heart models are needed to establish the correctness of more complex properties for pacemakers, we earlier developed a realistic heart model that addresses this issue [1]. The model was adapted from a sophisticated model that generates multi-channel electrocardiogram (ECG) based on nonlinear ordinary differential equations (ODEs) due to Clifford *et al.* [4]. To transfer to our setting, where we need to consider that the pacemaker is implanted in the heart tissue, we convert external ECG signals into

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action potential signals read by implanted sensors. A unique feature of the model of [1] is that the heart can probabilistically switch between normal and abnormal beat types, in a manner that can be learnt from patient data. We performed quantitative, probabilistic verification by analysing the composition of the pacemaker model of [6] and the heart model against typical correctness properties such as (i) whether the pacemaker corrects faulty heart beats, maintaining normal heart rhythm of 60-100 beats per minute (BPM), and (ii) that the pacemaker does not induce erroneous heart behaviours (that is, it does not overpace the heart unless necessary). These were implemented based on the probabilistic model checker PRISM [9] and MATLAB.

One of the shortcomings of the heart model in [1] is that it does not capture the electrical conduction system of the heart, and specifically the delays in the action potential signal as it is propagated from cell to cell.

This paper reports on a model-based framework for software quality assurance for cardiac pacemakers developed in Simulink and described in [3]. We instantiate the framework with a physiologically-relevant heart model built as a network of cardiac cells. The heart model is inspired by that of [7], except that we represent it as a network of input-output hybrid automata, instead of timed automata, and enhance it with stochasticity. The model enables the modelling of both diseased and normal rhythms, and can be adapted to exhibit random delays in the timing of events that are patient-specific. We implement the heart model in Simulink and validate it against the pacemaker models of [7], demonstrating basic safety properties of the pacemaker by means of probabilistic approximate model checking, with encouraging results. We also provide experimental results for advanced properties, including pacemaker mediated tachycardia correction and detailed analysis of energy consumption. This paper extends the results reported in [2]. The outcome of the research is a comprehensive model-based framework based on Simulink suitable for simulation, as well as quantitative verification, of pacemakers. The interested reader is referred to [3] for more detail.

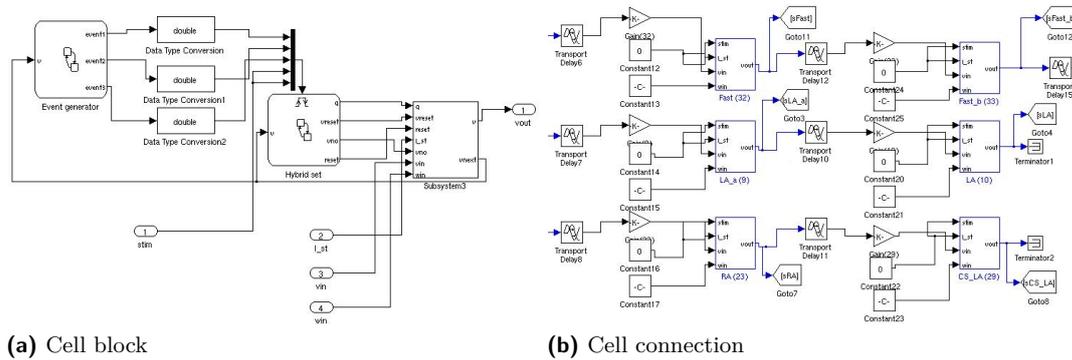
2 Quantitative Verification

We implement both the heart model and the pacemaker model in Simulink.

Fig. 1a shows the Simulink implementation of a cardiac cell. The cell is implemented by means of three Simulink blocks: *Event generator*, *Hybrid set* and *Subsystem*. The *Event generator* block is responsible to generate the input events to the cell. The *Hybrid set* implements the cell hybrid automaton model. The *Subsystem* block performs the integration procedure to compute the voltage level of the cell. Fig. 1b shows a network of six cells. Each cell block is composed from the three sub-blocks shown in Fig. 1a and connected to other cells through delay and gain components.

We run a set of experiments on a faulty heart to verify that the pacemaker restores the normal heart beat. In Fig. 2a we depict two signals. The first one (in blue) denotes the action potential generated by the *natural pacemaker cell* of the heart situated in the atrium. More precisely, we have three beats in six seconds, which is approximately 30 beats per minute. The number of heart beats is thus too slow and needs the intervention of the pacemaker. The second signal (in red) denotes the action potential from one of the cardiac cells situated in the ventricle. This is the signal which is captured and paced by the pacemaker.

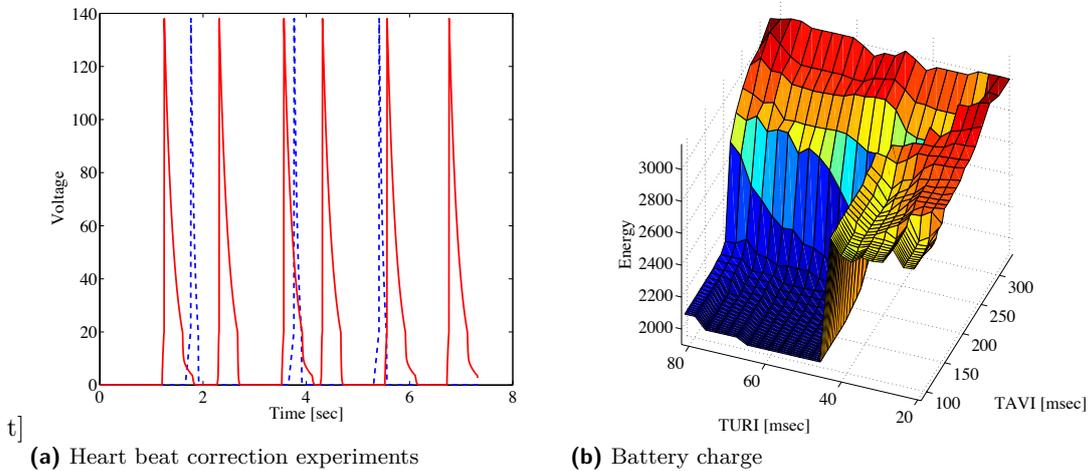
The second set of experiments depicts the relation between different programmable parameters of the pacemaker and the battery charge. In Fig. 2b we depict the battery charge in a period of 1 min when the programmable parameters TAVI and TURI of the pacemaker are varied.



(a) Cell block

(b) Cell connection

■ Figure 1 Cardiac cell model.



(a) Heart beat correction experiments

(b) Battery charge

■ Figure 2 Experiments.

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