Estimation and Verification of Hybrid Heart Models for Personalised Medical and Wearable Devices*

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Abstract. We are witnessing a huge growth in popularity of wearable and implantable devices equipped with sensors that are capable of monitoring a range of physiological processes and communicating the data to smartphones or to medical monitoring devices. Applications include not only medical diagnosis and treatment, but also biometric identification and authentication systems. An important requirement is personalisation of the devices, namely, their ability to adapt to the physiology of the human wearer and to faithfully reproduce the characteristics in real-time for the purposes of authentication or optimisation of medical therapies. In view of the complexity of the embedded software that controls such devices, model-based frameworks have been advocated for their design, development, verification and testing. In this paper, we focus on applications that exploit the unique characteristics of the heart rhythm. We introduce a hybrid automata model of the electrical conduction system of a human heart, adapted from Lian et al [8], and present a framework for the estimation of personalised parameters, including the generation of synthetic ECGs from the model. We demonstrate the usefulness of the framework on two applications, ensuring safety of a pacemaker against a personalised heart model and ECG-based user authentication.

Recent technological advances have spurred a huge growth in apps and wearables for use in health monitoring. They employ a multiplicity of noninvasive sensors, e.g. accelerometers and miniature cameras, that can read physiological indicators, wirelessly send data to smartphones and analyse it not only to record trends (e.g. fitness bands), but also to support decision making for diagnosis and intervention. The success in miniaturisation of electronics has led to novel variants of traditional medical devices being introduced on the market, such as leadless cardiac pacemakers that can be implanted inside the human heart (e.g. Nanostim) and implantable glucose monitors that transmit data to a wristwatch to alert the wearer about any undesirable trends (e.g. Minimed). Applications are not limited to the medical field, and include also emerging technologies for biometric user identification and security, such as wristbands that periodically check the electrocardiogram (ECG) of the user to produce a template authentication signal (e.g. the Nymi band).

An important requirement for wearables is their personalisation, namely, the ability for the device to adapt to the physiology of the human wearer based on the person's individual characteristics. Personalisation is typically achieved via an appropriate parameterisation of a model of the physiological process, through parameter estimation

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and parameter synthesis techniques. Automation of personalised delivery of medical treatment is a major challenge; for example, rate-adaptive pacemakers are able to vary the rate of pacing depending on the activity and age of the patient [6], but insulin pumps still rely on human supervision. Another important role of personalised devices is in device safety assurance, where they can be used to faithfully reproduce the unique characteristics of the wearer in real-time for the purposes of testing.

Undoubtedly, personalised medical wearable and implantable devices are an important step towards achieving personalised healthcare. However, major advances are necessary to realise this vision, ranging from technological (miniaturisation, low-power circuits), software technologies (design automation, code generation, integration), to regulatory and legal frameworks (FDA approval, certification). This paper is concerned with model-based design and verification techniques for ensuring safety and effectiveness of personalised devices based on the bioelectrical activity of the heart.

We focus on the hybrid automata framework for closed-loop quantitative verification of cardiac pacemakers introduced in [4,7]. This was extended in [5] with techniques to automatically synthesise optimal timing delays to minimise energy consumption, and in [2] with a hardware-in-loop simulator to evaluate embedded pacemaker software on low-power hardware. However, personalisation was not supported.

In this paper, we extend the framework of [4,7] as follows. We introduce a new hybrid heart model encoded in Simulink/ Stateflow and develop techniques to personalise the model through parameter estimation based on ECG data. We implement methods to produce synthetic ECGs that are characteristic for the given individual, and also to compare different ECG patterns. We consider two applications: verification of safety properties for a pacemaker against a personalised heart model, and biometric identification based on matching the wearer's signature with ECG data acquired for recognition. Further details on the methods and results are provided in the technical report [1].

1 Heart Model and Personalisation

We define a new heart model that includes the key components of the electrical conduction system of the human heart (Fig. 1) and is a hybrid automata translation of the model in [8].

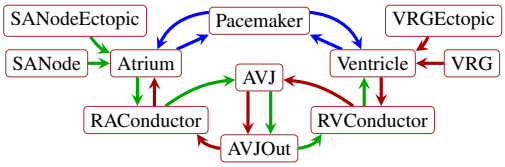
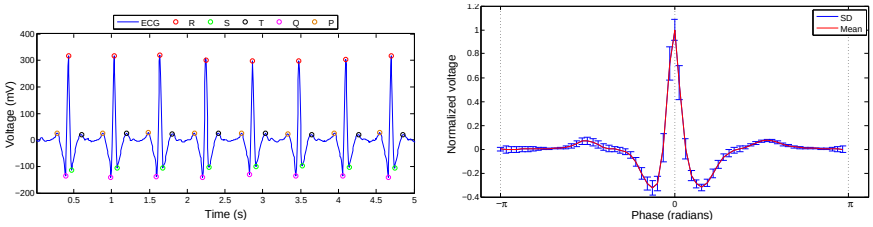


Fig. 1: Heart model.

The model can reproduce antegrade conduction (green arrows in the figure), arising when a stimulus is generated by the sinoatrial (SA) node and is propagated towards the ventricle passing through atrium and the atrio-ventricular (AV) node. The impulse can also start from the ventricle (either intrinsically by component VRG or artificially by the pacemaker) and propagate in the opposite direction (retrograde conduction, red arrows). The transmission of cardiac waves between the atrium and ventricle is mediated by the AV node component (AVJ) and by intermediate conduction nodes (AVJOut, RAConductor and RVConductor). The model can reproduce, among others, ectopic beats (through components SANodeEctopic and VRGEctopic) and the collision of cardiac waves leading to fusion beats. The artificial pacemaker [3] is connected to

the atrium and ventricle, and can both sense and stimulate them by delivering electrical impulses. An important feature of the model is the ability to generate *synthetic ECG signals*, which are used for parameter estimation and authentication. An ECG signal can be broken into five different waves, namely P, Q, R, S and T. Each wave is a simple bell-shaped curve which we reproduce in the synthetic signal by associating events in the heart model with Gaussian functions.

Estimation from ECG data. To achieve a personalised model, we need to estimate parameter values so that the synthetic ECG is close to the input signal. The first steps are filtering and processing of the signal and detection of the ECG waves (Fig. 2a). Detected peak locations, widths and amplitudes can be directly mapped to some parameters of the model, e.g. the SA node frequency, overall AV conduction time and ventricular refractory time. Instead, some other parameters that cannot be inferred in this way are estimated using a Gaussian process optimisation (GPO) approach. Specifically, we seek to minimise the statistical distance between the input signal and the synthetic signal generated by the model with the parameters sampled in the GPO loop. In order to compute the distance, the signals are mapped into a single (statistical) ECG waveform centred around the R wave (the highest peak, see Fig. 2b).



(a) (b)

Fig. 2: Processed signal and detected peaks (a). Statistical ECG waveform (b).

2 Applications and Discussion

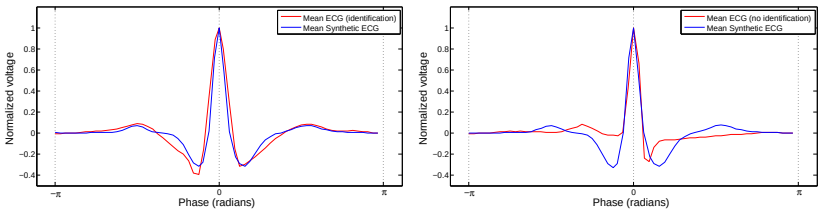
Pacemaker Verification. We study two properties related to two common heart conditions: bradycardia, i.e. slow heart rate, and AV block, i.e. conduction defect in the AV node. For the first property we query the probability that bradycardia episodes never occur, i.e. that the time between two consecutive ventricular events is always below some threshold. The second property requires correct conduction of the AV node, i.e. that the time between two consecutive atrial and ventricular events always lies in a given interval. Table 1 shows the results of the probabilistic verification for these properties on a healthy heart, a heart with arrhythmia (bradycardia for the first property and AV block for the second), and the same defective heart but with the pacemaker attached.

Property	Healthy	Arrhythmia	With Pacemaker
$P_{=?}G^{<60000}(Vget \Rightarrow F^{<1100}Vget)$	0.99997 ± 0.0012	0.360607 ± 0.000015	$1 - 0.00003$
$P_{=?}G^{<60000}(Aget \Rightarrow F^{[100,200]}Vget)$	0.946454 ± 0.0005	$0.0 + 0.000005$	0.875494 ± 0.0008

Table 1: Results of pacemaker verification. $Aget$ and $Vget$ indicate the presence of an atrial and ventricular beat, respectively.

Note that the pacemaker can correct the two defective dynamics, since it ensures that the first property holds with probability 1 and the second with probability above 0.87.

Authentication. We show how the synthetic ECG generated by the personalised model can be used as a template for authentication purposes. This is based on computing its distance with the recognition ECG acquired for the identification. If the obtained score is small enough (e.g. not exceeding 50% of the score obtained in the estimation phase), the authentication is successful. Fig. 3a shows an example of successful identification when the ECGs for model estimation and authentication come from the same patient[1], while Fig. 3b shows how authentication failed with a signal from a different patient[2].



(a) Successful. Distance: 0.42 (b) Failed. Distance: 0.78

Fig. 3: Matching synthetic and recognition ECGs for authentication.

Discussion. In this work, we presented methods to derive personalised heart models from data and showed their usefulness in the safety verification of pacemaker devices and in the ECG-based authentication. Besides enabling formal verification and synthesis [4,2], code generation and modularity, our formal model-based framework is sufficiently general to support, at the same time, other kinds of physiological systems and medical devices. This would enable improvement of the authentication performance by combining the ECG with other biometrics (e.g. fingerprints or iris) [9], and ultimately verification of the collective behaviour of multiple interconnected devices in a closed-loop with a highly-personalised model of the human physiological system.

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