Model-Based Conformance Testing for Implantable Pacemakers

George Chen
BME/EE 2015, Johns Hopkins University

Graduate Student: Zhihao Jiang, CIS, UPenn
Advisor: Rahul Mangharam, ESE, UPenn
Problem

- Over 200,000 pacemakers recalled in 1990-2000 were a result of **software issues**
- There is currently **no systematic way** to test the safety of pacemaker software.

Goal:

**Develop tools and methodologies** to test and formally verify whether the software in medical devices is safe.
Model-Based Design Framework

Medtronic Test File 46

- Formal Verification
  - Properties checking

- Model Testing
  - Simulation in Simulink

- Model Testing
  - Properties checking

- Physical Testing
  - Black box & White box testing

- Random Heart Model
- UPPAAL Model
- UPP2SF
- Stateflow Model
- RTWEC
- HDL Coder

initializing...

- starting test
- Pacemaker paced ventricle on time at t=0. (Expected at t=0. Misalignment: 0)
- sent ventricular signal at t=50.
- sent atrial signal at t=200.
- Pacemaker paced atrium on time at t=750. (Expected at t=750. Misalignment: 0)
- Pacemaker paced ventricle on time at t=1001. (Expected at t=1000. Misalignment: 1)
Implementation

Graphic User Interface

Hardware Testing Platform

Pacemaker Output
Acknowledgements

- Prof. Rahul Mangharam
- Zhihao Jiang
- Abhijeet Mulay
- mLab members
- Dr. Jan Van Der Spiegel
- National Science Foundation