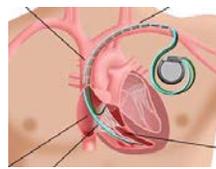# Model-Based Conformance Testing for Implantable Pacemakers

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Background

-The increasing complexity of pacemaker software has resulted in **an increase in the number of life-threatening malfunctions**

-The percentage of medical device recalls due to *software-related issues increased from 10% to 21%* [1]

-There currently is **no systematic way** to evaluate the safety of pacemaker software.

Research Goals

-**Develop tools and methodologies** to test and formally verify whether the software in medical devices is safe within the closed-loop context of the patient.

-**Develop a test generation algorithm** that generates test cases for open loop and closed loop scenarios for the heart model and pacemaker model.

-**Implement a test platform** in hardware and test hardware pacemaker implementations.
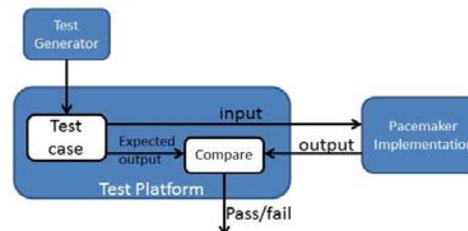
Methods

-We propose **model-based conformance testing** based off the work of Pajic et.al [2]:
1) Convert a pacemaker specification to a Timed Automata model representation.
2) Evaluate the safety of the specification by formally verifying the pacemaker model in closed-loop with a model of the heart.
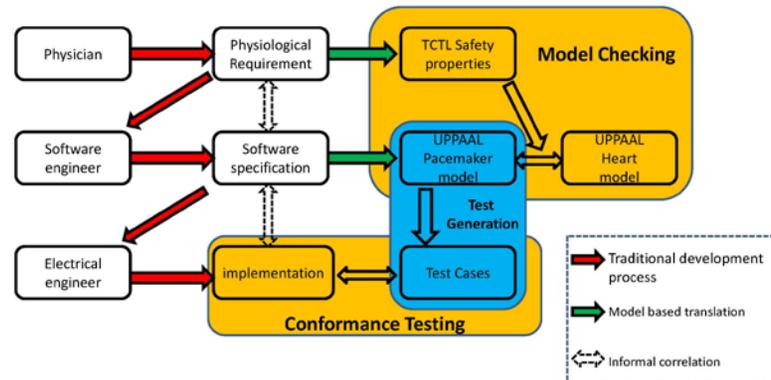
Testing Framework

The testing framework consists of a *Test Generator* and a *Test Platform*.
The Test Generator generates a series of test cases that satisfy certain coverage criteria for the pacemaker.
The Test Platform executes each test case to the pacemaker implementation evaluates if the pacemaker passed the test cases.

Results

-**A Matlab Timed-Automata model of a pacemaker and test platform** with error reporting has been made.
-**A hardware platform for the test platform and pacemaker implementation** are currently in progress.
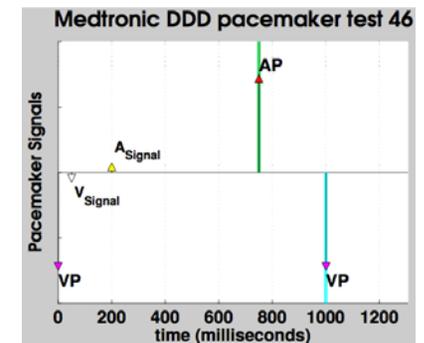
Future Work

-Complete the **hardware test platform and pacemaker implementation**
-Quantify coverage criteria of test cases.

References

[1] "List of Device Recalls, U.S. Food and Drug Admin. (last visited Jul. 19, 2012)."
[2] Miroslav Pajic, Zhihao Jiang, Oleg Sokolsky, Insup Lee, Rahul Mangharam, "From Verification to Implementation: A Model Translation Tool and a Pacemaker Case Study", The 18th IEEE Real-Time and Embedded Technology and Applications Symposium (RTAS 2012), 2012.

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