A Simple Pacemaker Implementation

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Problem Statement

Implementation of the behavior of a pacemaker described in the Pacemaker requirements document by Boston Scientific, with the need for demonstrating:

- Utility: pacemaker performs useful actions;
- Safety: it doesn' t perform harmful actions.

Background

A pacemaker is a device that's placed under the skin of the chest or abdomen to help control heart arrhythmias. Depending on which arrhythmias are present, modern pacemakers provide different functioning modes that perform different kinds of therapeutic behavior.

The goal of the project is to build a simple but complete implementation of a subset of the pacemaker' s function modes.

AAT
A: Atrium chamber paced
A: Atrium chamber sensed
T: Triggered response

VVI
V: Ventricle chamber paced
V: Ventricle chamber sensed
I: Inhibited response

DDD
D: Both chambers paced
D: Both chambers sensed
D: Tracked response

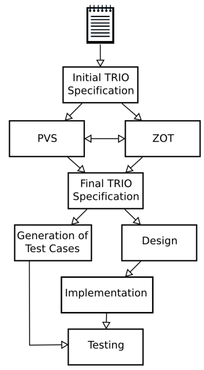
Triggered response means that a sense in a chamber shall trigger an immediate pace in that chamber.
Inhibited response means that a sense in a chamber shall inhibit a pending pace in that chamber.
Tracked response means that an atrial sense shall cause a tracked ventricular pace after a programmed AV delay, unless a ventricular sense was detected beforehand.

Finally to avoid false sensing, refractory periods follow atrial and ventricular events during which senses in the affected chamber are ignored.

Solution

The artificial pacemaker is a system whose behavior needs to be accurately and completely specified in order not to lead to possible mistakes.

Our approach made extensive use of formal methods: pacemaker properties formalized by means of the TRIO+ language for the specification of the system, and validated through the use of the SAT checker called Zot and the specification and verification system called TVS (TRIO/PVS).

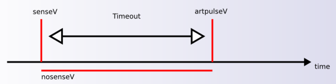


Starting from the natural language specification of the pacemaker, a TRIO formal specification was produced. ZOT and PVS were used to validate the initial formal specification. These tools are complementary. ZOT automatically checked the satisfiability of the system, and produced example behaviors that were useful in understanding the axiomatization. Then PVS was used to prove the target properties of the system. Each time a new axiom was introduced, the validation process was repeated.

Finally, the Design of the system followed directly from the TRIO formal specification.

```
AXIOM Alw(VVI IMPLIES
(Lasted(NOT senseV,TIMEOUT
IFF artpulseV))
```

VVI Pacemaker provides artificial pulses if and only if it does not sense any ventricular event (senseV) for TIMEOUT=1/LRL time instant.
In other words the device is called to produce artificial pulses if a natural heart beat does not occur within TIMEOUT since the previous heart beat (sense or pace) to resume the heart rate (HR, inverse of time interval between ventricular senses) over the target value of the pacemaker, called lower rate limit (LRL).

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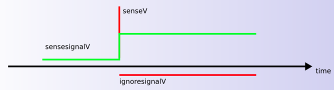
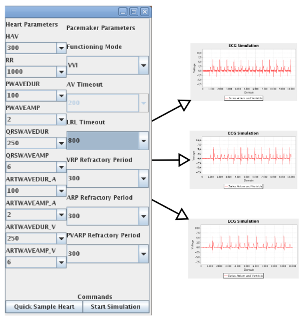
AXIOM 1: Alw( sensesignalV AND
NOT ignoresignalV IFF senseV)
AXIOM 2: Alw( senseV IMPLIES
NowOn(ignoresignalV))
```

These axioms defines what is a ventricular event (senseV). (1) A ventricular event occurs if the pacemaker senses a signal in the ventricle chamber (sensesignalV) and it is not ignoring the signal in that chamber (ignoresignalV).
(2) If we detect a ventricular event, then we will ignore the ventricle signal for a certain amount of time.



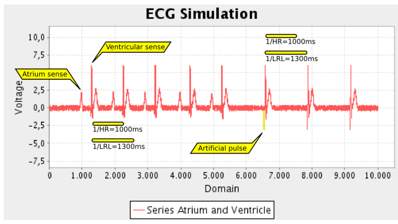
Implementation

For the purpose of this project a JAVA simulation of the pacemaker system was implemented. The simulation allowed the project to proceed on time and is sufficient to represent most of the aspects of the pacemaker problem.
Given as input the desired parameters of the heart, and the set of pacemaker parameters, the program produces an ECG that shows how the pacemaker regulates the behavior of the patient's heart.



Simulator JAVA classes exactly represent the main pacemaker components:

- the Pulse Generator;
- a class modeling the heart behavior;
- Device Control Monitor (DCM) ;
- ECG as output of simulator.



VVI pacemaker action: At the beginning the heart has a natural pace which is regular and admissible. After a while the device is called to perform ventricular articial pulses to resume the heart rate (HR) over the lower rate limit (LRL).

JAVA methods corresponds to system properties directly translated from axioms formalized in TRIO.
Following such an approach, the simulation helps to ensure the utility and safety the system is required to achieve.

Conclusions

The resulting pacemaker performs well on the provided test cases and could be used by a physician to explore how the pacemaker reacts to different heart behaviors.
The big advantage of formal methods and of the tools used is that they help us to develop a complete understanding of the system we are designing. This has a cost in terms of time, but then the implementation phase is straighforward and less prone to errors.