Title

A Simple Pacemaker Implementation

Abstract

Boston Scientific has made available a natural language requirements document for a previous generation pacemaker. This document has become the basis for a Grand Challenge, and is ideal for realistic, safety-critical student projects. Pacemakers operate under a number of "modes" that are fully explained in the requirements document. This particular project will require teams to implement only a few of those modes, namely "VVI", "DDD" and "DDDR".

Introduction

Pacemakers use electrical impulses to regulate the beating of the heart in cases where the heart is damaged and is not able to maintain an adequate heart rate. The pacemaker is implanted surgically in the patient's body in such a way that electrical leads attached to the pacemaker allow the pacemaker to monitor the heart's behaviour, and the pacemaker can then regulate the patient's heart-beat if necessary. The software embedded in the pacemaker is responsible for implementing the therapeutic behaviour. There are clear safety implications. If the pacemaker does not adequately regulate the heart-beat the patient is at risk. If the pacemaker "paces" the heart when it is not necessary, it has an adverse effect on the long-term health of the heart. In general, we have to differentiate between "efficacy" (it does helpful actions) and "safety" (it doesn't do harmful actions).

This project will require participants to implement behaviour described in the PACEMAKER Requirements Document [1]. The software *must* implement three modes described in [1], VVI, DDD, and DDDR, although teams *may* implement all of the modes and features in [1]. The modes basically determine the type of pacing the device must implement at any point in time. The specifics of the project are described in the following sections. The PACEMAKER device hardware is proprietary and not available to participants. However, a reference hardware platform is available. The reference hardware was designed by a senior student ECE design group at the University of Minnesota. Use of the reference hardware manifests system behaviour essential to develop, test, evaluate, and compare results. Teams may build their own hardware platform (specifications of the hardware platform are available). Alternatively, teams may purchase the hardware platform from the hosts of the PACEMAKER Challenge – The Software Quality Research Laboratory (SQRL) at McMaster University, Canada. Details concerning the hardware platform are provided below.

This project is a real-world example of a real-time safety-critical application. Final deliverables will be judged on this basis. Formal methods may help teams provide an appropriate level of assurance for their projects.

Application domain

As described earlier, the application is designed to be embedded in human patients. Aside from the safety implications, the software must be designed to minimise power requirements since the battery has to power the device for as many years as possible (minimum five years)..

Project goals

Intended output of the process

Project teams can choose the methods they think are appropriate for this application. Note that formal approaches are well suited to safety-critical applications.
The following are the minimal set of deliverables:

- Project Plan
- Requirements: Specific requirements for the project. These may be a subset of the requirements described in [1].
- Design Specification: Detailed design description of the component architecture to be implemented.
- Test Plan: Description of the tests to be performed on the component to be developed.
- Code
- Evidence that the implementation meets requirements.

Tools and standards

The reference hardware platform for the PACEMAKER Challenge and Project is based on the PIC18F4520 manufactured by Microchip.

There are two viable compilers for the PIC18F4520:

(1) The open source SDCC - Small Device C Compiler
http://sdcc.sourceforge.net/

(2) Microchip's MPLAB C18 compiler
http://www.microchip.com/stellent/idcplg?IdcService=SS_GET_PAGE&nodeId=1406&dDocName=en010014&part=SW006011
It is free for academic use and the one the designers of the hardware platform used to test the platform.

Complete Gerber files for the manufacture of the reference hardware platform will be available on the PACEMAKER Challenge web site. Teams may then choose to manufacture their own hardware platforms based on the published reference hardware, or purchase assembled versions of the reference hardware platform from SQRL. Estimated cost is $350 CDN. Details will be posted on the PACEMAKER web site.

Interaction between stakeholder and developing teams

Teams are encouraged to interact with the contact group via email (sqrl@cas.mcmaster.ca). In particular, the student team will be required to:

- submit a proposed project plan before beginning
- provide progress reports and relevant information about the project status every month

General information regarding PACEMAKER (the complete system) will also be available on the PACEMAKER Challenge web site at http://sqrl.mcmaster.ca/pacemaker.htm

[1] The PACEMAKER Requirements document is available at:
http://sqrl.mcmaster.ca/pacemaker_spec.htm