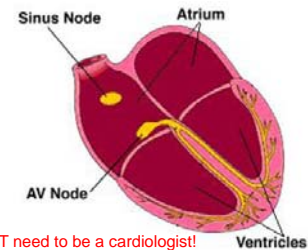


CS5219 Term Project Pacemaker: Modeling and Verification

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Human Heart



You do NOT need to be a cardiologist!

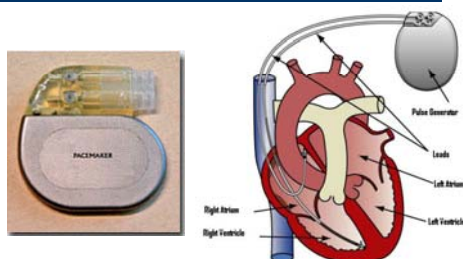
Natural Pacemaker

- An electric signal (pulse) is generated at the Sinus Node which stimulate left/right atrium to contract
- AV Node receives the signal, and after a delay (AV delay), it causes left/right ventricle to contract
- Automatically responds to body's changing need for oxygen

Bradycardia

- The beats per minute (bpm) rate of the heart is under the expectation (e.g., 60 bpm)
- Natural pacemaker is malfunctioning
 - No pulse (signal) is generated by Sinus node
 - Or signal is not strong enough to stimulate the AV node
- Medical solution: artificial pacemaker

Pacemaker



Pacemaker

- Medical device which uses electrical impulses to fix abnormal heart rate
- Implanted in to patient body, configured according to the patient needs
 - Maintain adequate heart rate
 - Monitor patient's activity, dynamically change the heart rate requirement

Pacemaker Components

The diagram illustrates the components of a pacemaker system. On the left, a heart is connected to 'Leads' which interface with the 'Pulse Generator ("The Device")'. Below the generator are an 'Accelerometer (rate adaptive pacing)' and a 'Donut magnet (Magnet testing, e.g. battery)'. On the right, 'Telemetry' connects the device to a 'Device Controller Monitor (DCM)'. The DCM handles 'Parameter setting, updating, monitoring functions.' The entire system is labeled 'Within the patient'.

* By J. Fitzgerald @VSRnet Workshop at ABZ 2008

Pacemaker Components

- Device:
 - Pulse generator controller: maintain AV synchrony
 - batteries
- Device Controller-Monitor (DCM)
- Leads: wires that both sense and discharge electric pulses.
- Accelerometer: unit inside the device measuring body motion.

Pacemaker Formal Methods Challenge

- Hosted by SQL (Software Quality Research Laboratory)
 - <http://surl.mcmaster.ca/pacemaker.htm>
- Based on a released informal specification of a previous generation of pacemaker by Boston Scientific
 - Spec.: http://surl.mcmaster.ca/pacemaker_spec.htm
 - Wiki: <http://www.cas.mcmaster.ca/wiki/index.php/Pacemaker>
- Deliverables: from formal specification to complete pacemaker software running on specified hardware

Goal of the Term Project

- Model (part of) the pulse generation controller with formal specification language (Promela)
- Use model checker (Spin) to verify the correctness and desired properties of your model

Model Overview [3]

The flowchart shows the interaction between four main components:

- Environment (heart activity)**: Sends 'Heart pulse' to the **Sensor (pulse sensing + activity sensing)**.
- Sensor (pulse sensing + activity sensing)**: Sends 'Pulse sensing' to the **Pulse Generation (PG)** and 'Activity information' to the **Rate Controller (XXXR mode)**.
- Rate Controller (XXXR mode)**: Sends 'Rate interval' to the **Pulse Generation (PG)**.
- Pulse Generation (PG)**: Sends 'Sensing or not' back to the **Sensor**.
- A **Global timer** is also shown, connected to the Sensor and Rate Controller.

Architecture

- **Sequential model:**
 - timer->heart->sensor->rate controller(optional)
 - >PG->timer
- **Concurrent model:**
 - timer || heart || sensor || rate controller || PG
 - (Concurrent processes are considered to execute interleaving with nondeterministic)
 - Synchronization and atomic actions may be needed

Bradycardia Operating Modes

	I	II	III	IV(optional)
Category	Chambers Paced	Chambers Sensed	Response to Sensing	Rate Modulation
Letters	O – None A – Atrium V – Ventricle D – Dual	O – None A – Atrium V – Ventricle D – Dual	O – None T – Triggered I – Inhibited D – Tracked	R – Rate Modulation

- Total 18 available working modes
 - DDDR, VDDR, DDIR, DOOR, VOOR, AOOR, VVIR, AAIR, DDD, VDD, DDI, DOO, VOO, AOO, VVI, AAI, VVT and AAT

Response to Sensing

- No Response To Sensing (O)
 - Pacing without sensing is asynchronous pacing. During asynchronous pacing, paces shall be delivered without regard to senses
- Triggered Response To Sensing (T)
 - During triggered pacing, a sense in a chamber shall trigger an immediate pace in that chamber.

Response to Sensing

- Inhibited Response To Sensing (I)
 - During inhibited pacing, a sense in a chamber shall inhibit a pending pace in that chamber.
- Tracked Response To Sensing (D)
 - During tracked pacing, an atrial sense shall cause a tracked ventricular pace after a programmed AV delay, unless a ventricular sense was detected beforehand.

Programmable Parameters

- LRL (Lower Rate Limit) - number of pace pulses delivered per minute in the absence of sensed activity in an interval starting at a paced event.
 - LRL interval: Longest safe interval (in ms) between two consecutive paces: 60000/LRL
- URL (Upper Rate Limit)
 - URL interval is the minimum time between a ventricular event and the next ventricular pace.

Programmable Parameters

- AV Delay: the shortest period from an atrial event to a ventricular pace.
- Atrial Refractory Period: for single chamber atrial modes, this is the time interval following an atrial event during which time atrial events shall not inhibit or trigger pacing

Programmable Parameters

- Please refer to [1] for all programming parameters and relevant operating modes
 - Read [2] and [3] for examples
 - You can use the nominal values (page 34 [1])
- You do **NOT** need to model all parameters listed in [1]
 - Depend on which modes you will model
 - If you fail to model any of the (necessary) parameters of a mode, try to discuss the reasons

Model Global Timer

```

Timer++; /*increase timer by 1 millisecond*/
/*you may want to maintain a timer for a specific
programmable parameter*/
if
::AVD_Timer >= 0 -> AVD_Timer ++; /*activate*/
::else -> ; /*inactivate*/
fi;
    
```

* You may use the same (or different) AVD_Timer in Heart and PG components, depending on your model

Model Heart Activity

```

if
:: heart == nondeterministic ->
if
::(Timer - lastPace == NR) -> lastPace = Timer; AVD_Timer = 0;
if
:: pulseA ! 1;
:: /*do nothing*/
fi;
:: (AVD_Timer == AVD) ->
if
:: pulseV ! 1; AVD_Timer = -1; /*inactivate AVD_timer once a V pulse occurs*/
:: /*do nothing*/
fi;
:: heart == dead -> ...
:: heart == missV -> ...
fi;
    
```

Incomplete model

Model Sensor

```

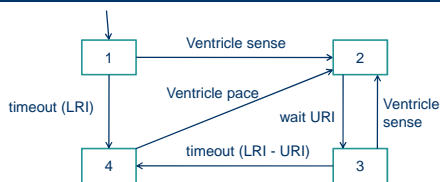
/*ASensor*/
if
:: (mode == XAXX || mode == XDXX) ->
do
:: pulseA ? p -> senseA ! 1;
od;
:: else -> ;
fi;
    
```

- Similarly for the VSensor

Example: VVI Mode

- V: Pace the ventricles
- V: Sense the ventricles
- I: During inhibited pacing, a sense in a chamber shall inhibit a pending pace in that chamber.

Example: VVI Mode [3]



LRI = 60000 / lower rate limit : maximum interval between two paces
 URI = 60000 / upper rate limit : minimum interval between two paces

timeout() in Spin

- No concept of “real-time” in Promela
- In Promela, timeout is a predefined global read-only variable, that has the value true in all global system states where no statement is executable in any active process, and false in all other states
- Carry no parameter. ~~timeout(5)~~

Safety Properties

- Pacemaker is a safety-critical system
- Design your own safety-properties and verify them on your model
 - No deadlock (Spin automatically checks deadlock)
 - Lower and upper rate limits
 - Verify correctness of modeling the programmable parameters
 - E.g., V pulse always occurs AVD ms after an A pulse --> $[(AVD_Timer \leq AVD)$

Safety Properties

- The cardiologist decides the operating mode based on patient's symptom
 - You may have different requirements for different mode
- Some modes do not work in certain heart condition (environment)
 - E.g., AAT mode may not work for dead heart (no pulse generated)
- It is possible to use the verification results to guide the mode selection

Term Project

- Assessment (total 30 marks)
 - 15 marks for results and final report
 - 8 marks for innovative techniques,
 - 5 marks for final presentation,
 - 2 marks for interim report.

Minimum Expectations - 1

- 1 person project
 - Reasonable modeling and verification effort using SPIN checker.
 - Any abstractions used in modeling must be clarified properly.

Minimum Expectations - 2

- 2 person project
 - 1 person project expectations +
 - Using the SPIN model as a guide to generate C code.
 - You will also then be able to argue how/why you could use the SPIN model as guidance and the links between requirements, model and code.

Minimum Expectations - 3

- 3 person project
 - 2 person project expectations +
 - one group member writing the code without going through modeling and the two codes will be compared systematically to clarify coding errors or errors in understanding the requirements.

Project Deliverables

- One single **.zip** file includes
 - A report in **.doc** or **.pdf** format
 - Your pacemaker model:
 - **.pml** file(s) contain the your Promela model (necessary comments will be a plus)
 - **LTL** files contain properties to be verified

Project Deliverables: the Model

- **Sequential** model
- Consider the following heart behaviors as environment
 - Nondeterministic
 - Dead heart (no pulse signal generated)
 - Missing V pulse (signal is not strong enough to stimulate the AV node)
- Design your own safety properties (in separated LTL files) and verify them

Project Deliverables: the Model

- You should model at least **SIX** operating modes, **including** VOO, VVI, DDD, and AAT
- Model the XXXR mode (e.g., DDDR) earns you **bonus** credits ([1] Section 5.7)
- Model the Hysteresis pacing in any relevant modes earns you **bonus** credits ([1] Section 5.8)

Project Deliverables: Report

- Group members and Matric #
- Present all modes you have modeled
 - Explanation in text and/or **state diagram** (see [2] and [3] for examples)
- A table lists all programmable parameters you have modeled in your Promela specification
 - For each parameter, list in which mode(s) it is used

Project Deliverables: Report

- Summarize the critical properties you have designed to verify (see [3] for examples)
 - It is also interesting to discuss if any of the properties fails to hold
- Anything you want to explain/discuss about your modeling/experiences
- No more than **20 pages, single column**

Conclusion

- Interesting project: real-world problem
- Difficulties:
 - unfamiliar application domain
 - Informal, incomplete, or even contradictory specification
 - Hint: self-learning/research, read the supplementary references

External References

- [1] Pacemaker informal specification
- [2] H Macedo, *Validating and Understanding Boston Scientific PACEMAKER Requirements*, Technical Report, Minho University, 2007
- [3] L. A. Tuan, M. C. Zheng, and Q. T. Tho, *Modeling and Verification of Safety Critical Systems: A Case Study on Pacemaker*, SSIRI, 2010
- [4] A Gomes and M Oliveira, *Formal specification of a cardiac pacing system*, FM, 2009
- [5] H Macedo, P Larsen, and J Fitzgerald, *Incremental development of a distributed real-time model of a cardiac pacing system using vdm*, FM, 2008