McMaster University

Model-Based Design Pacemaker

SFWRENG 3K04

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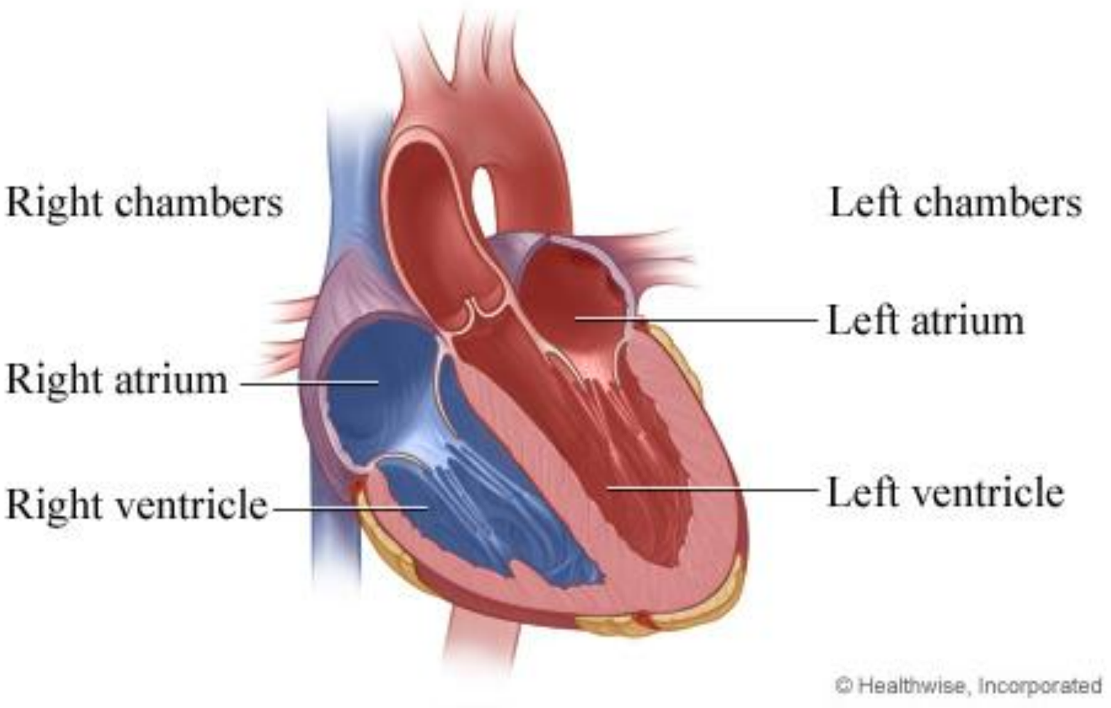
Overview

1. Cardiac Conduction System
2. Pacemaker Theory
3. Design considerations for pacemaker
4. The Project

1.

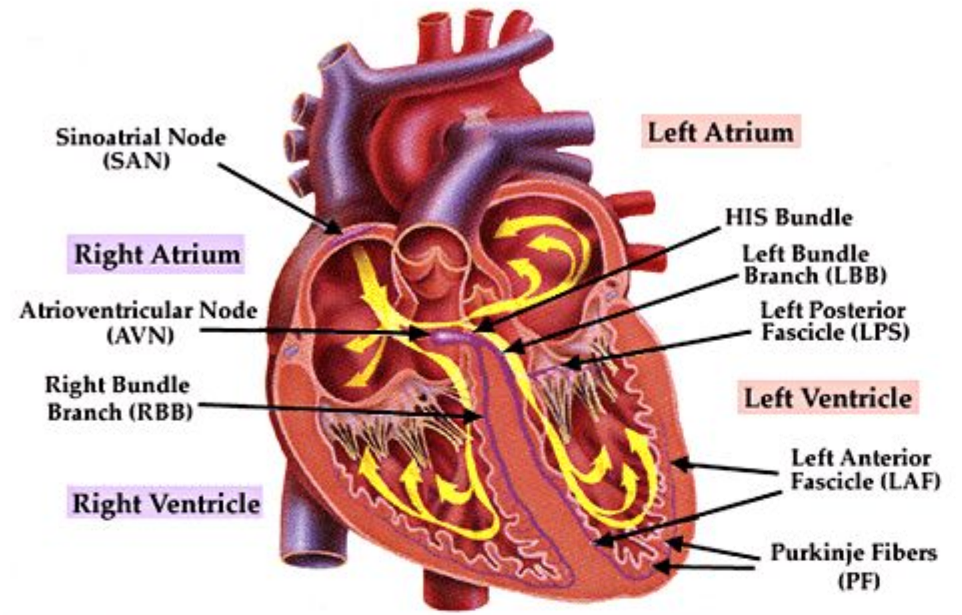
The Cardiac Conduction System (CCS)

Anatomy of the Heart



Cardiac Conduction System

- the bioelectrical network that makes your heart beat

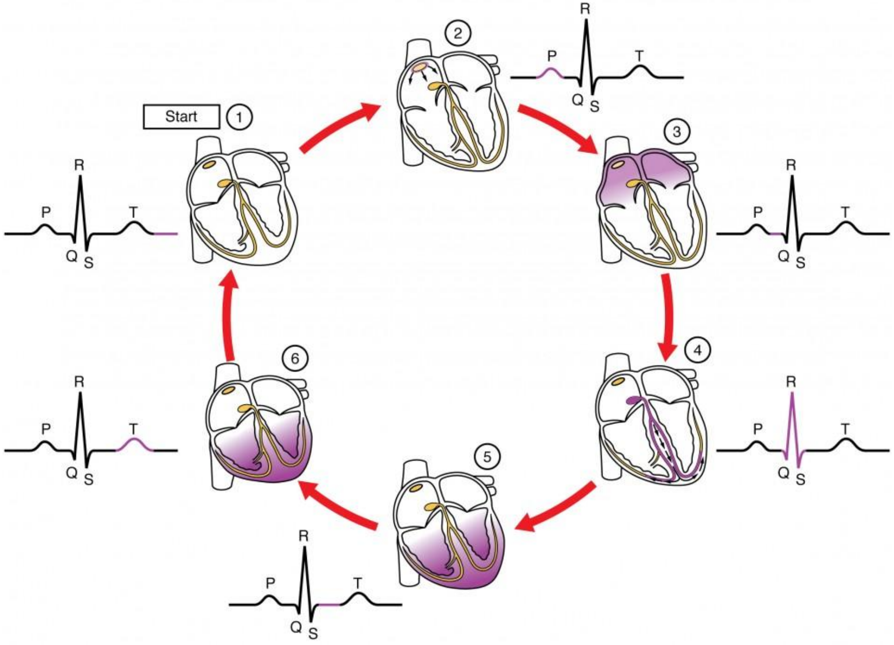


Cardiac Conduction System

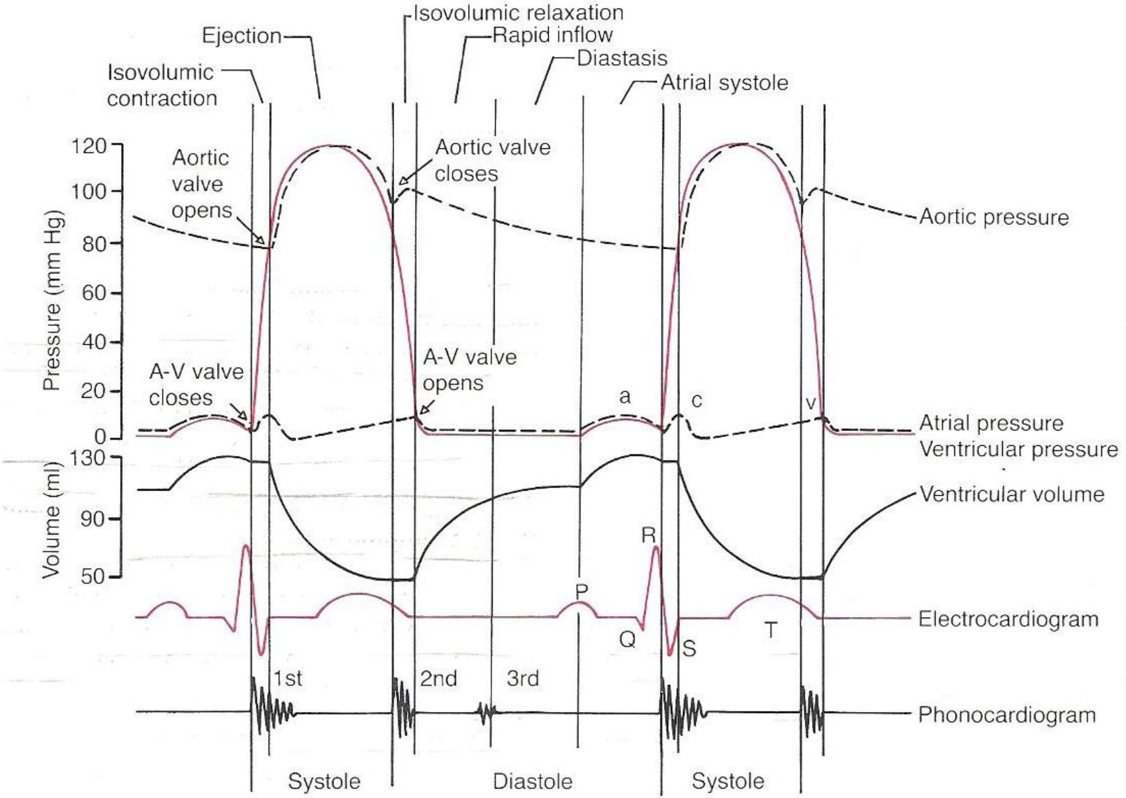
- The sinoatrial (SA) node is the heart’s natural pacemaker
- Components of the CCS send signals to heart muscles to cause them to contract

The Electrocardiogram (ECG)

- Records electrical activity in the heart using surface electrodes placed on the skin

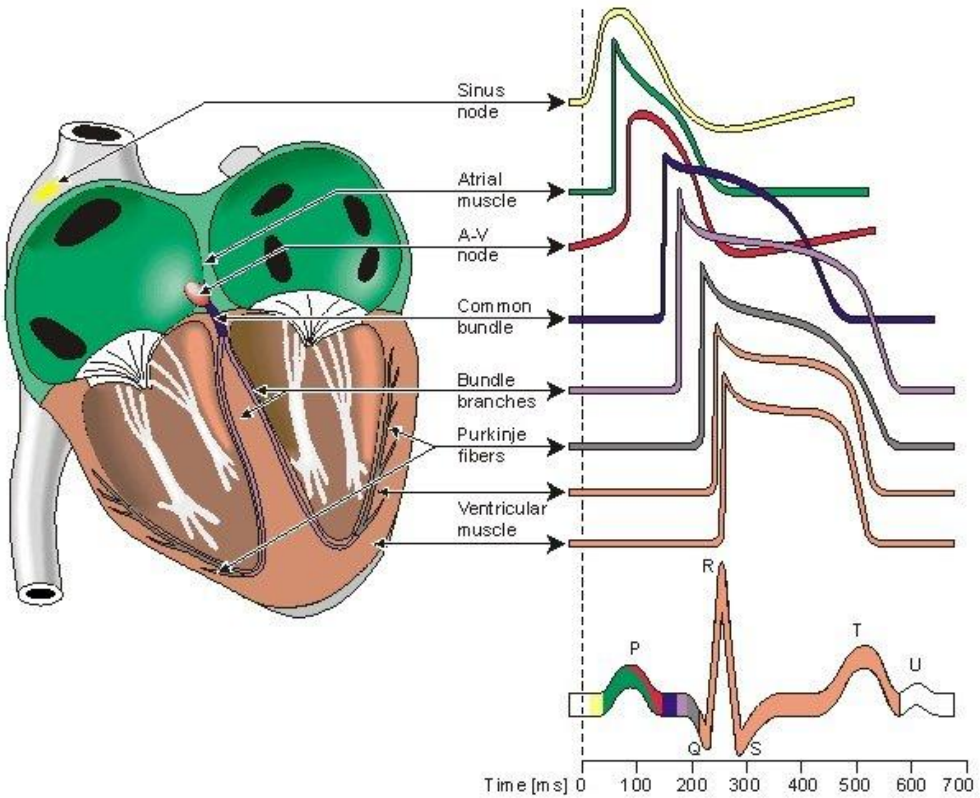


The Electrocardiogram (ECG)



Cardiac Conduction System

- Surface ECG signal is a sum of action potentials over all components of the heart



Conditions and Causes of Problems in the CCS

- SA node malfunction or muscle fibre blockage could result in:
  - Bradycardia - heart beats too slow
  - Arrhythmia - heart beats irregularly

- Caused by heart disease, congenital heart defects, medications or damage from cardiac surgery

2.

Pacemaker Theory

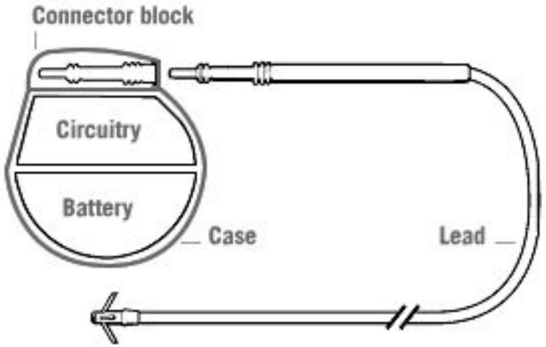
- What is a pacemaker?
- Pacemaker components
- Pacemaker implant procedure
- Pacemaker operating modes
- Pacemaker functions

The Pacemaker Is...

- A safety critical device implanted in the body that is used to monitor and regulate a patient’s heart rate by sending electrical pulses to the heart
- Used as a standard treatment for conditions such as arrhythmia and bradycardia

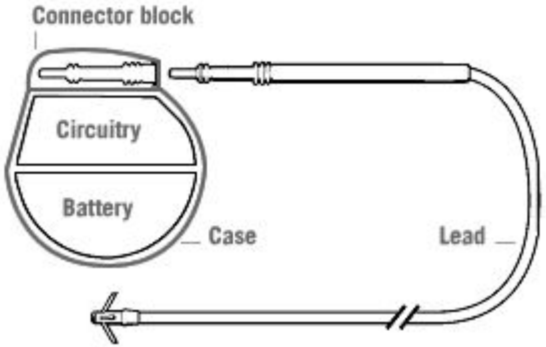
Pacemaker Components

- Pulse Generator ("the Can")
  - Lead connector block
  - Case
  - Battery
  - Circuitry
    - Components include: clock, telemetry antenna
    - Controls timing and intensity of electrical impulses

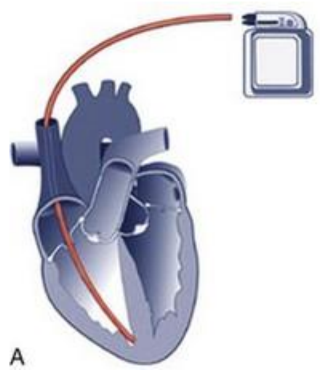


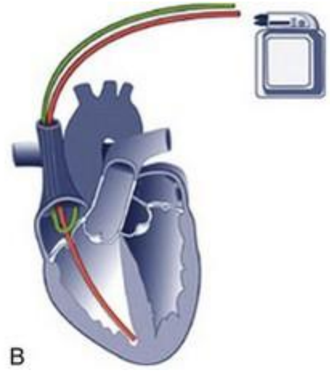
Pacemaker Components

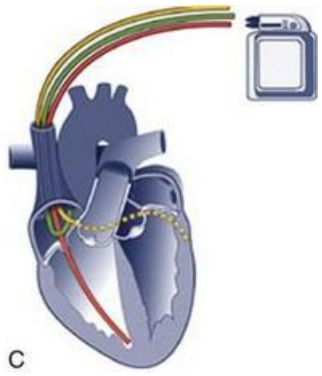
- Lead
  - Carries electrical stimulus to the heart
  - Carries information about heart's natural activity back to pacemaker



Pacemaker Pacing Systems







Single-Chamber Pacing System

Has 1 lead

- Lead placement: RA or RV
- Used to treat isolated SA node dysfunction with normal AV node conduction

Dual-Chamber Pacing System

Has 2 leads

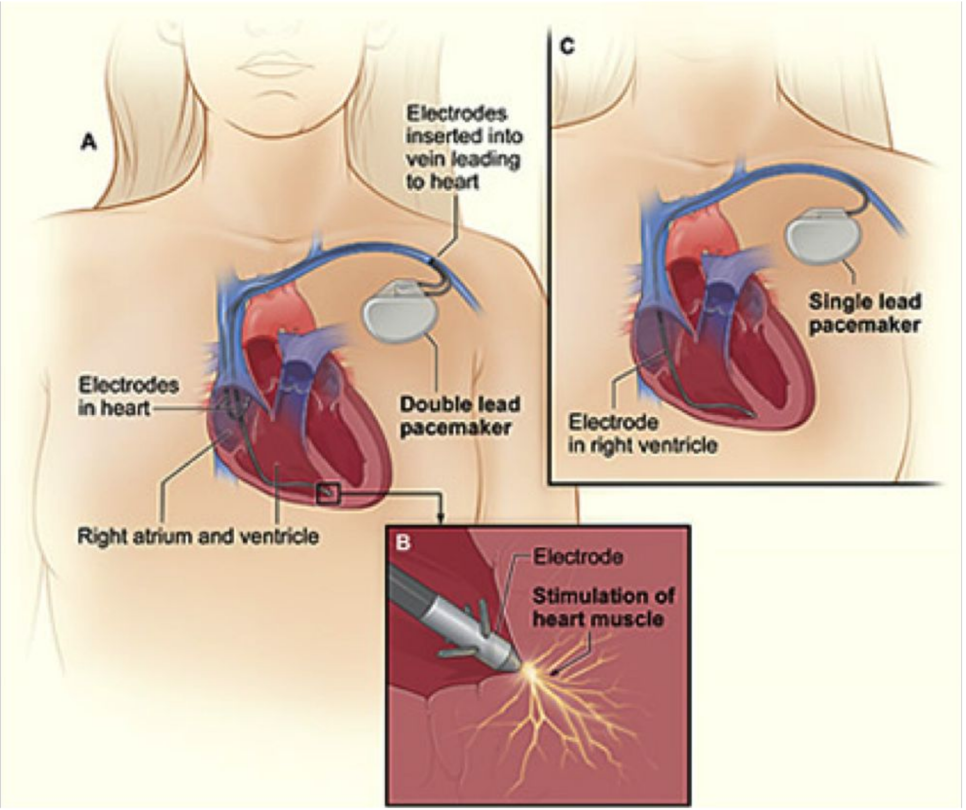
- Lead placement: RA and RV
- Used to treat both SA node dysfunction and poor AV conductivity

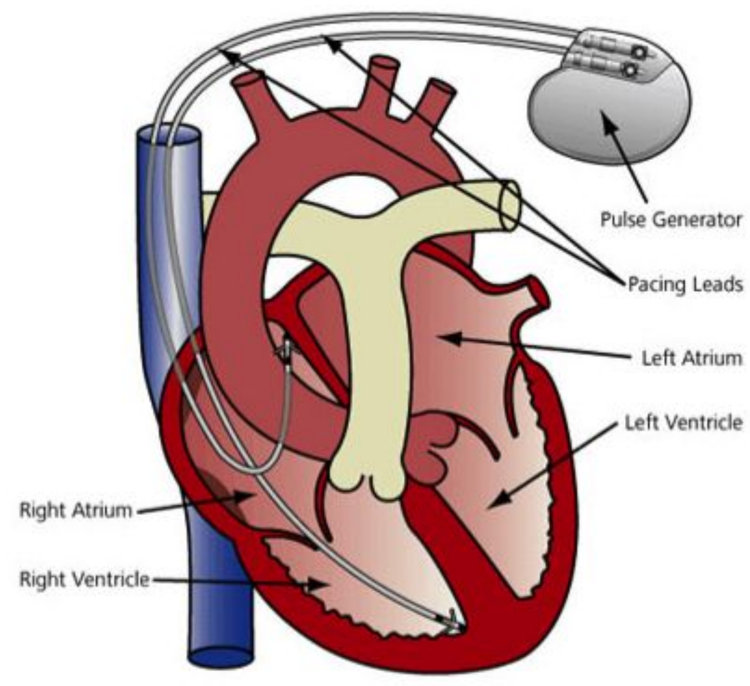
Biventricular Pacing System

Has 3 leads

- Lead placement: RA, RV and LV
- Used to synchronize ventricular contraction

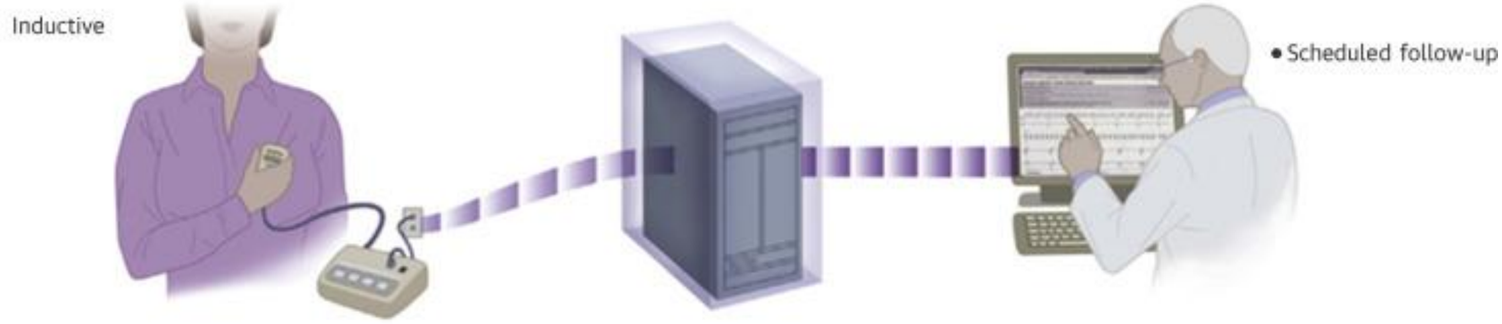
Pacemaker Implant Procedure





Pacemaker Implant Procedure

- Device Control Monitor (DCM) is used by the physician to make adjustments to the pacemaker settings



Pacemaker Operating Modes

Position:	I		II		III		IV		V	
Category:	Chamber(s) Paced		Chamber(s) Sensed		Response to Sensing		Rate Modulation		Multisite Pacing	
Letters Used:	O	None	O	None	O	None	O	None	O	None
	A	Atrium	A	Atrium	T	Triggered			A	Atrium
	V	Ventricle	V	Ventricle	I	Inhibited	R	Rate Modulation	V	Ventricle
	D	Dual A+V	D	Dual A+V	D	Dual T+I			D	Dual A+V
Manufacturers' Designation Only:	S	Single A or V	S	Single A or V						

Figure 5. North American Society of Pacing and Electrophysiology (NASPE) mode code.

Example

Describe the following pacemaker operating modes: VVI, VVT, DVTR & VVD.

Position:	I	II	III	IV	V
Category:	Chamber(s) Paced	Chamber(s) Sensed	Response to Sensing	Rate Modulation	Multisite Pacing
Letters Used:	O None	O None	O None	O None	O None
	A Atrium	A Atrium	T Triggered	R Rate Modulation	A Atrium
	V Ventricle	V Ventricle	I Inhibited		V Ventricle
	D Dual A+V	D Dual A+V	D Dual T+I		D Dual A+V
Manufacturers' Designation Only:	S Single A or V	S Single A or V			

VVI - Pace the ventricle synchronously. In the presence of a sensed ventricular signal, inhibit a pace in the ventricle.

VVT - Pace the ventricle synchronously. In the presence of a sensed ventricular signal, pace the ventricle.

DVTR - Pace the atria and ventricle synchronously. In the presence of a sensed ventricular signal, pace the ventricle. In addition, adjust the programmed paced heart rate in response to a patient's activity.

VVD - N/A (Dual Response To Sensing is restricted to dual chamber systems)

Example (cont'd)

Typically, trigger modes are used in conjunction with inhibit modes (i.e. if the SA node doesn't fire, we need to pace the atria. If the AV node doesn't conduct properly, then we need to pace the ventricle. Otherwise, we inhibit pacing the chambers). Why might a mode like VVT be used?

A mode like VVT might be used if the electrical stimulus sent to the ventricle fails to depolarize the ventricles and cause it to contract properly. A stimulus could be sent by the pacemaker to elicit ventricular contraction.

Pacemaker Functions

- Bipolar demand pacing
- Sensing
- Rate adaptive pacing
- Store and print diagnostic information

Demand Pacing

- Pacemaker regulates fixed heart rate and delivers pulse

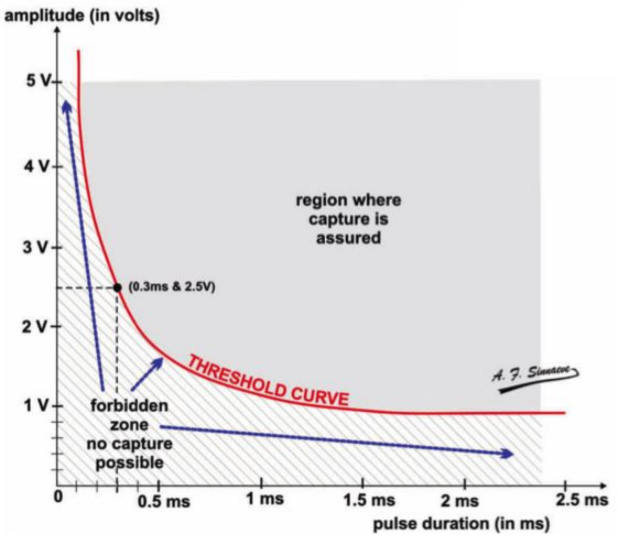


Figure 1: Strength-Duration Curve

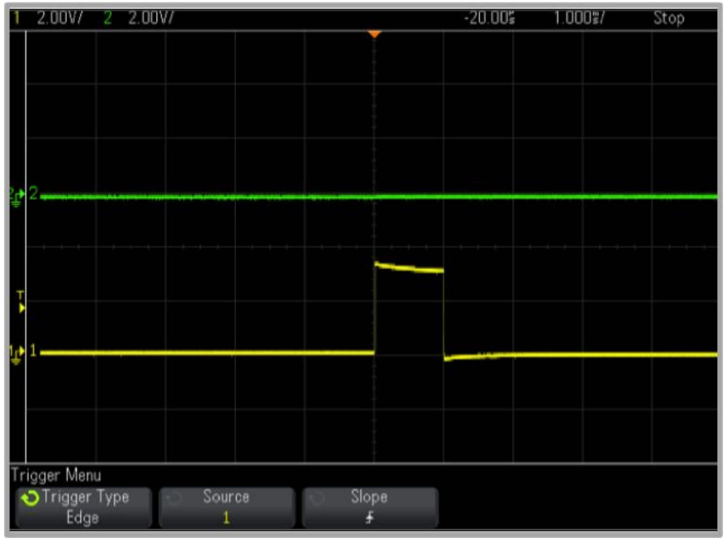


Figure 2: Waveform of output pulse

Sensing Basics

- Threshold
- Oversensing
- Undersensing

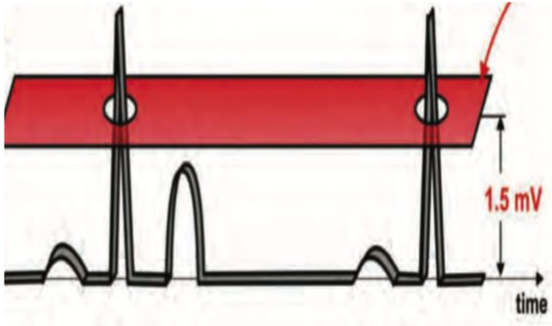


Figure 1: Example sensing threshold

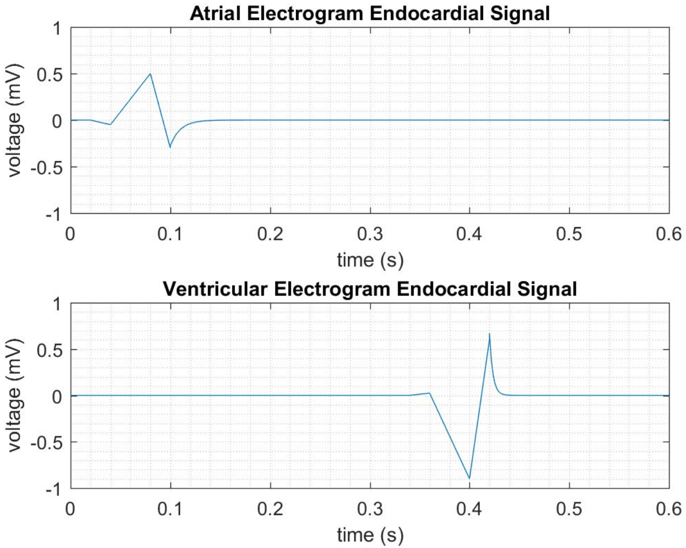
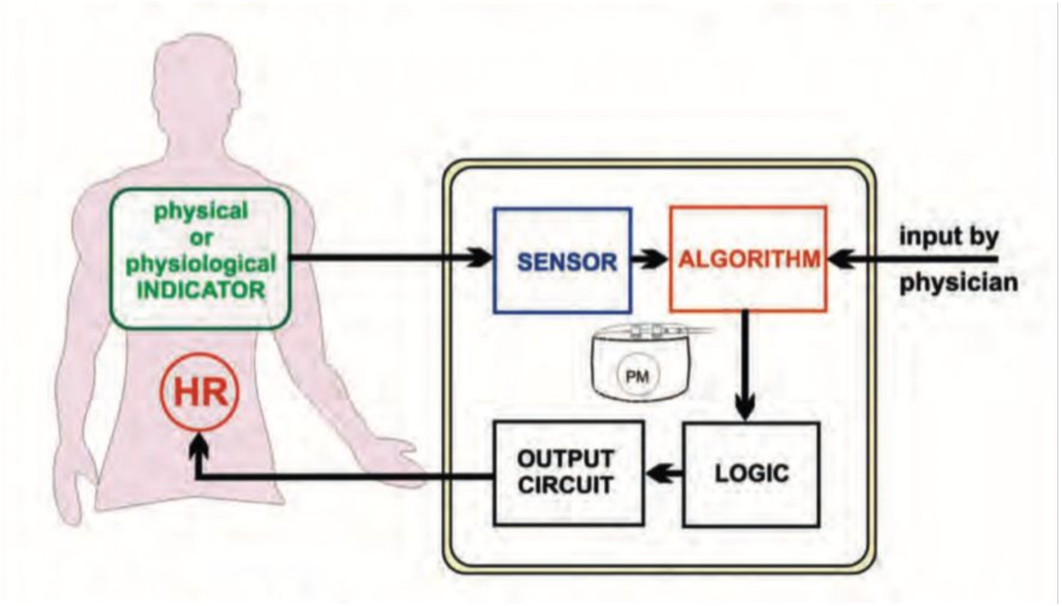


Figure 2: Sketch of atrial and ventricular electrogram

Rate Adaptive Pacing (open-loop)

- Treats chronotropic incompetence
- Measure changes in physical activity and adjust a patient's heart rate to respond accordingly



Rate Adaptive Pacing

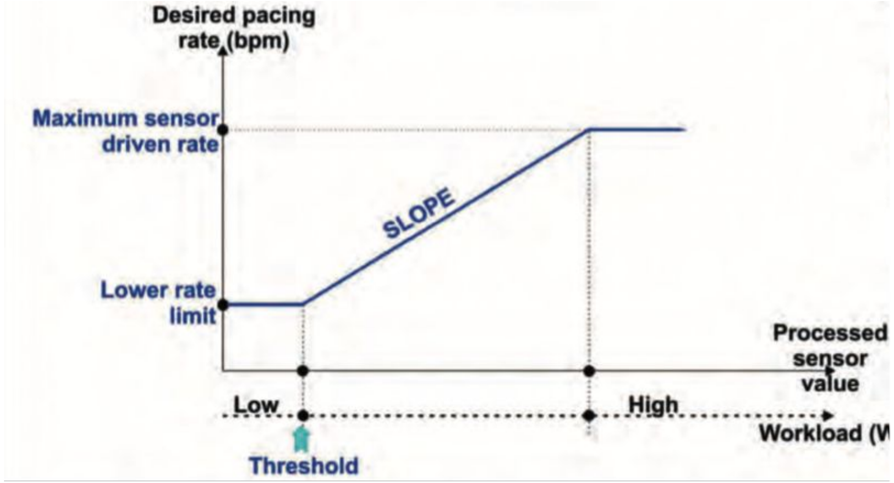


Figure 3: Rate adaptive pacing description

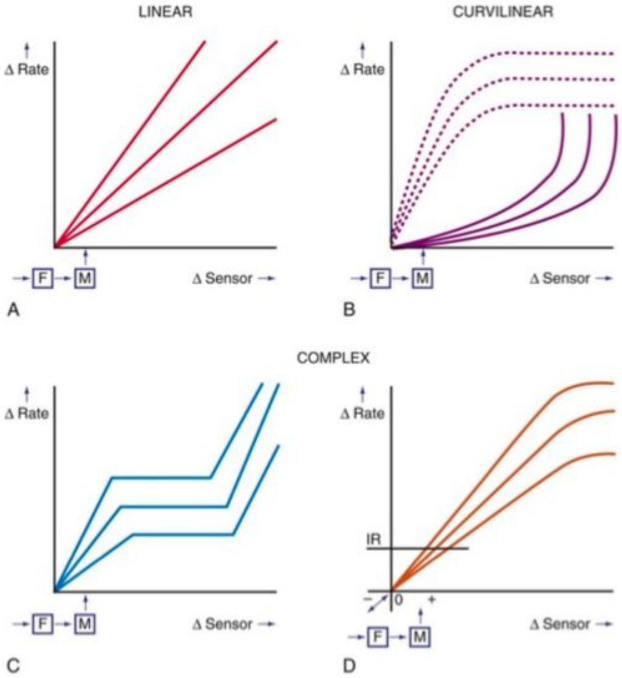
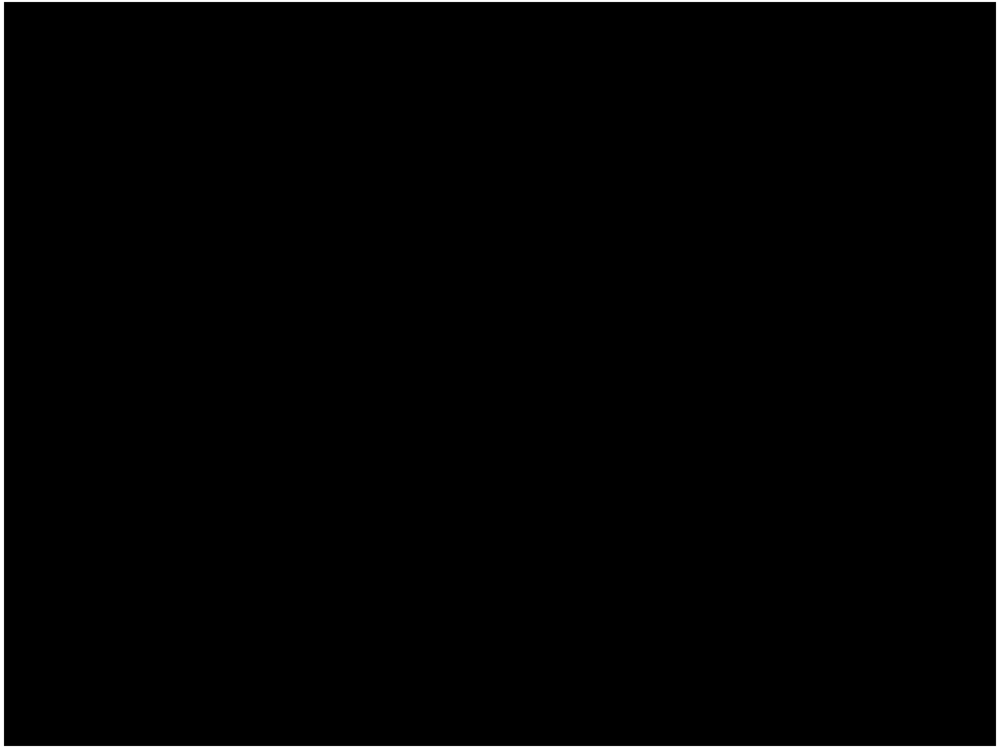


Figure 4: Typical rate response curves

Rate Adaptive Pacing (video)



3.

Pacemaker Design Considerations

Model-Based Design

- Pacemaker system is a real-time, safety critical device
- Pacemaker functionality can be described using Finite State Machines (FSM)
- Great need for reliable software specification, verification, validation and quality in today's medical devices
- Failure for software to meet safety and security standards can be fatal to the user
- FSM based formal methods improves software quality and design
- Other considerations: lifespan, lead redundancy, security

4.

The Project

- Overview
- Components
- Testing Environment

The Pacemaker Project

Vision: Improve familiarity with model-based design and apply principles of software design.

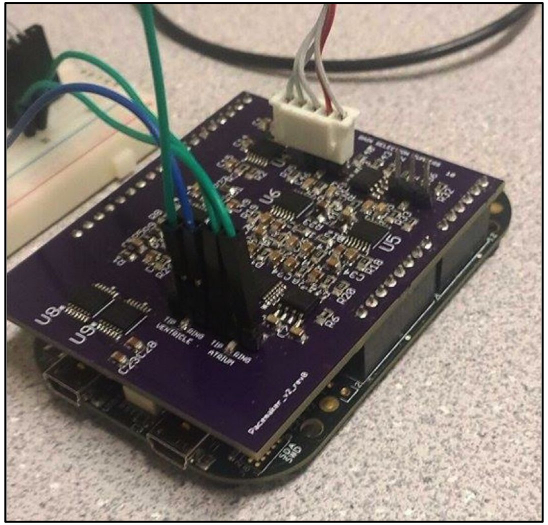
Goal: Design and implement a system that operates a cardiac pacemaker under the specified modes.

Deliverables: Refer to Assignment 1 outline.

System Components

FRDM-K64F Microcontroller

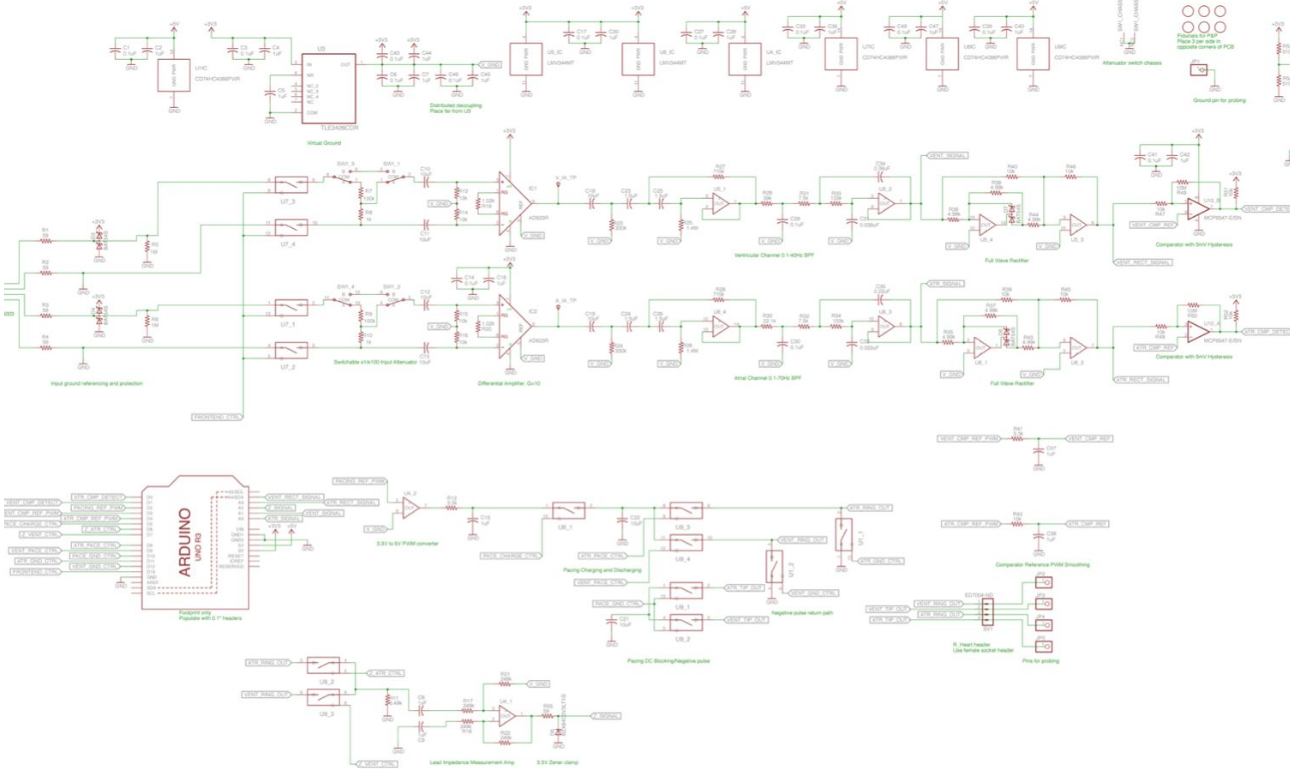
- ▷ Signal generation and computations
- ▷ Features:
  - ○ GPIO pins
  - ○ On-board accelerometer
  - ○ On-board magnetometer
  - ○ 16-bit ADC



The Shield

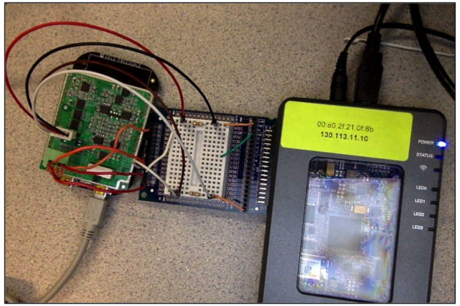
- ▷ Interfaces with FRDM-K64F
- ▷ Capable of dual chamber pacing and sensing
- ▷ Performs amplification, filtering and rectification

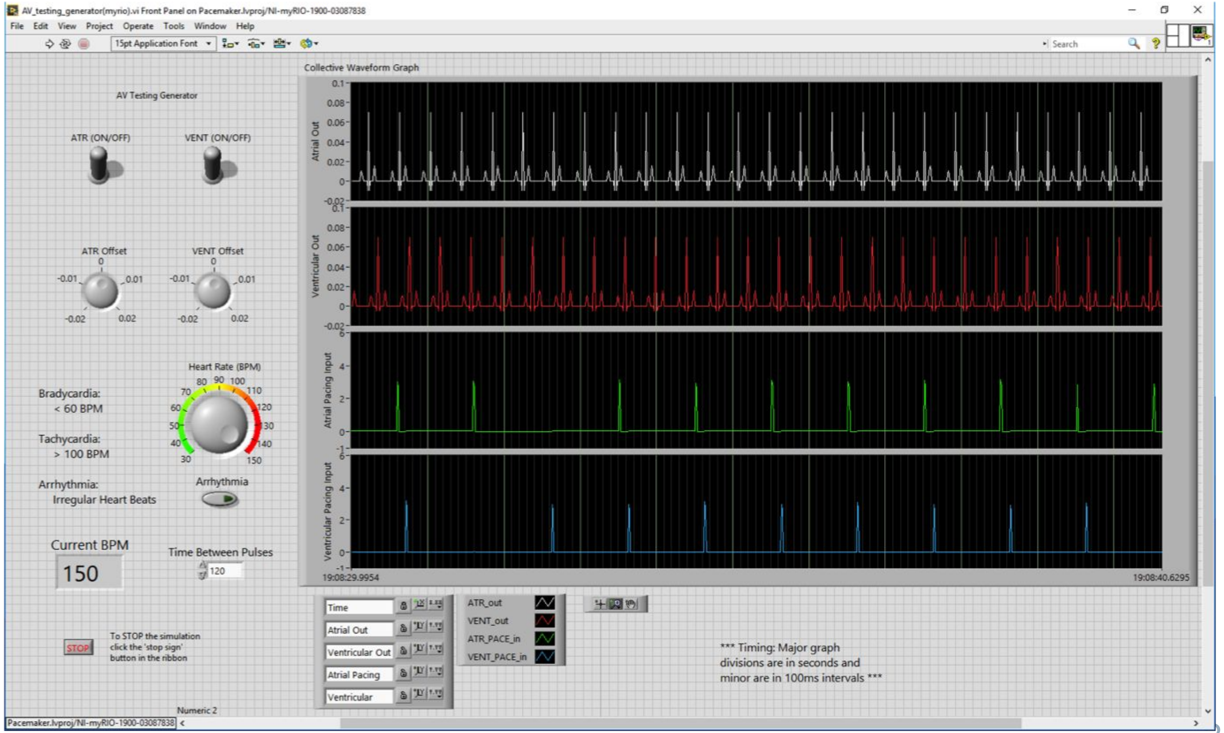
Shield Schematic



Testing Procedure

- Simulink debugging
- Labview test suite will be available in labs





Key Takeaways

1. What is a pacemaker and why is it important?
2. How does the pacemaker interact with the heart?
3. Why is the model-based design approach relevant for safety critical applications like the pacemaker?

Thanks for listening!

Any questions?