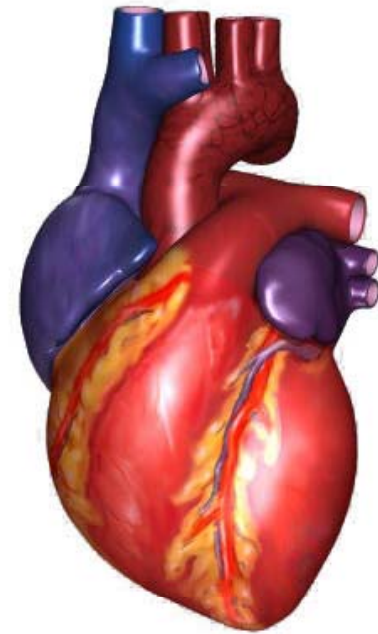


An Electrophysiological Heart Model for Formal and Functional Device Verification

Allison Connolly

BME 2010, Johns Hopkins University

Advisor: Rahul Mangharam, ESE, UPenn





Introduction



- FDA has no formal method for verifying medical device software
- Develop heart model as a testing tool
- Plug-and-play with devices, patients, and software
- Allows for testing and detection of malfunctions
- My role: start a new project





Motivation



Problem:

Over 200,000 cardiac medical devices recalled from 1990-2000 due to software.

From 1985-2005, nearly 30,000 deaths and 600,000 injuries from device failures.

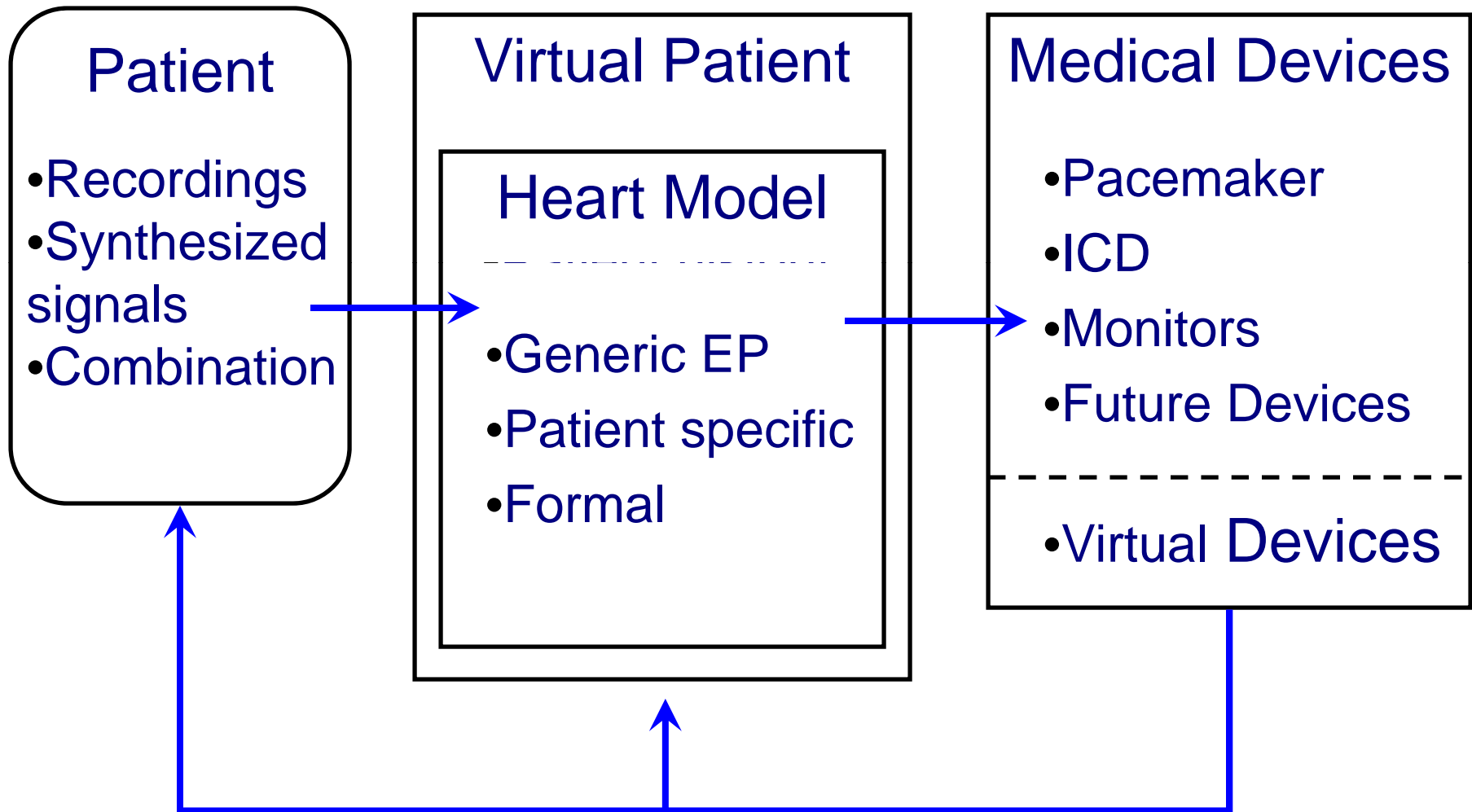
Goal:

Facilitate the design of bug-free medical device software.





Overview

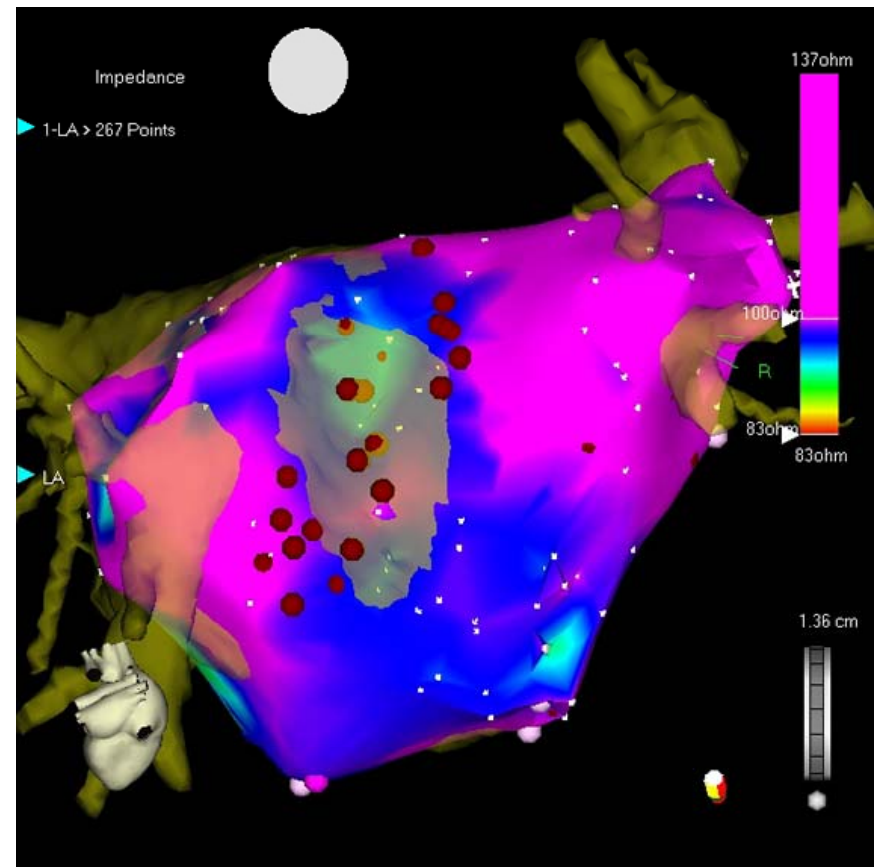




Background: Data Collection



- Electrocardiogram (ECG)
- Electrogram
- CARTO Mapping
- MRI images

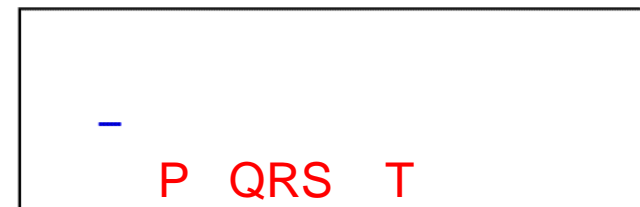
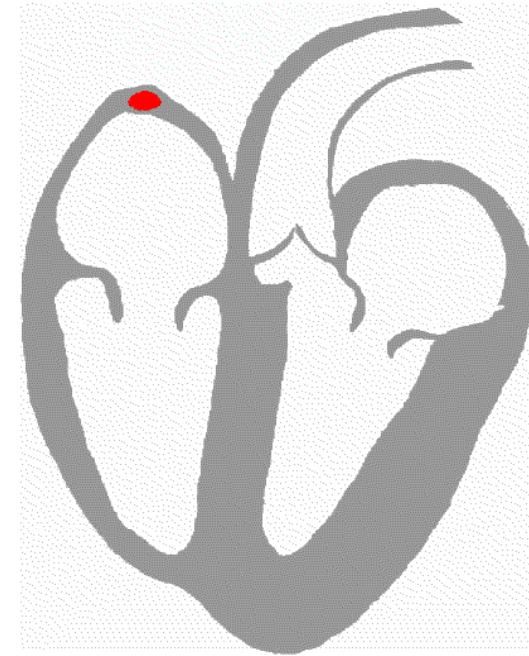




Background: ECG



- Electrocardiogram (ECG)
- Measures electrical activity of heart from surface of chest
- Up to 12 leads
- Diagnose arrhythmias and heart diseases

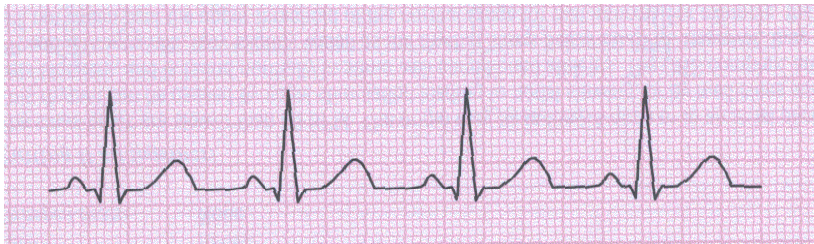




Background: ECG



Normal Sinus Rhythm



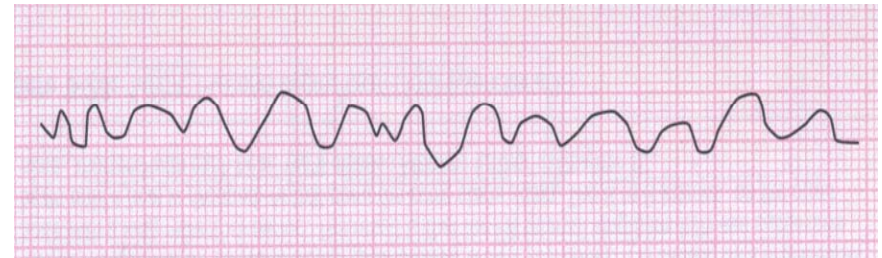
Atrial Fibrillation



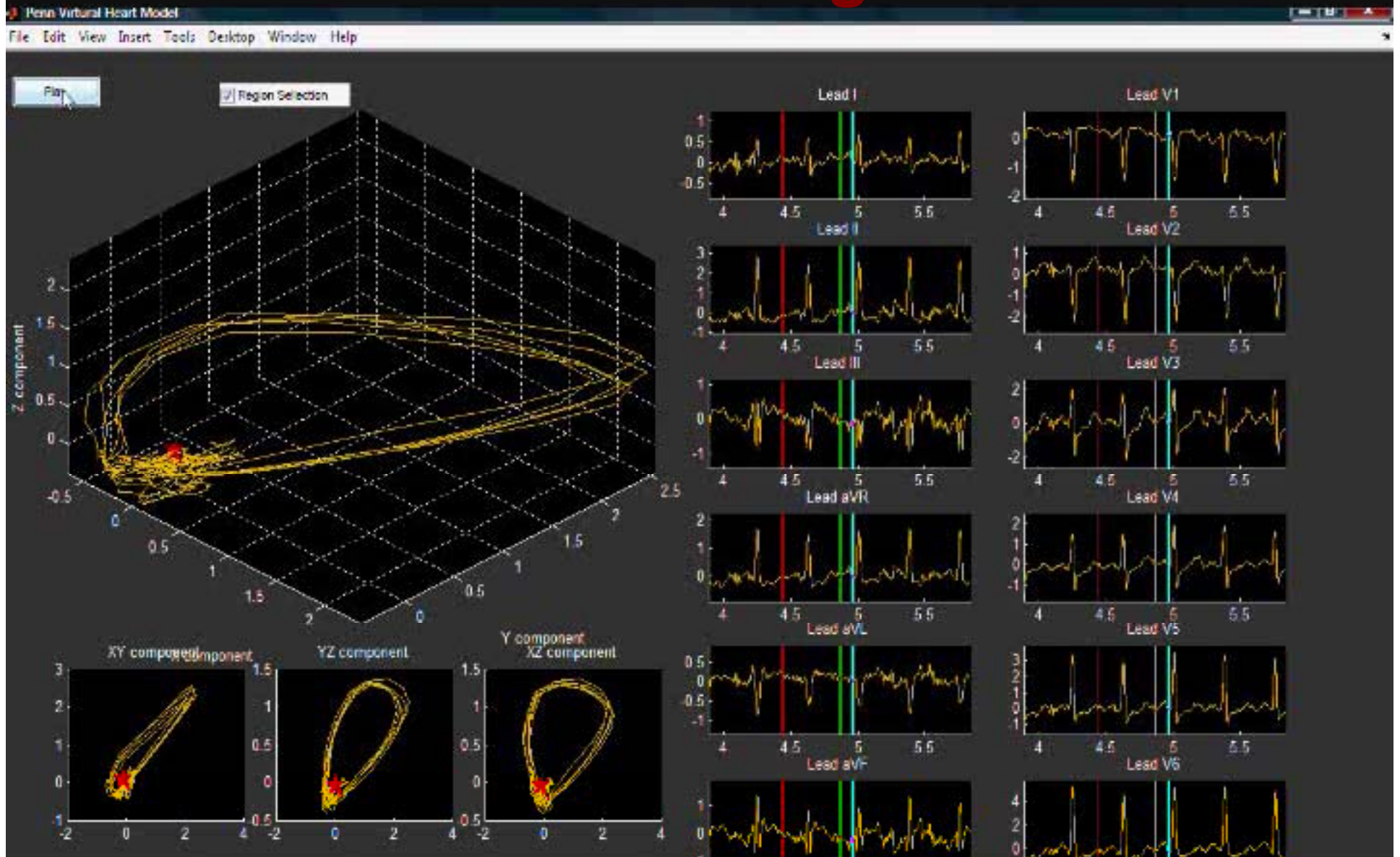
Ventricular Tachycardia



Ventricular Fibrillation

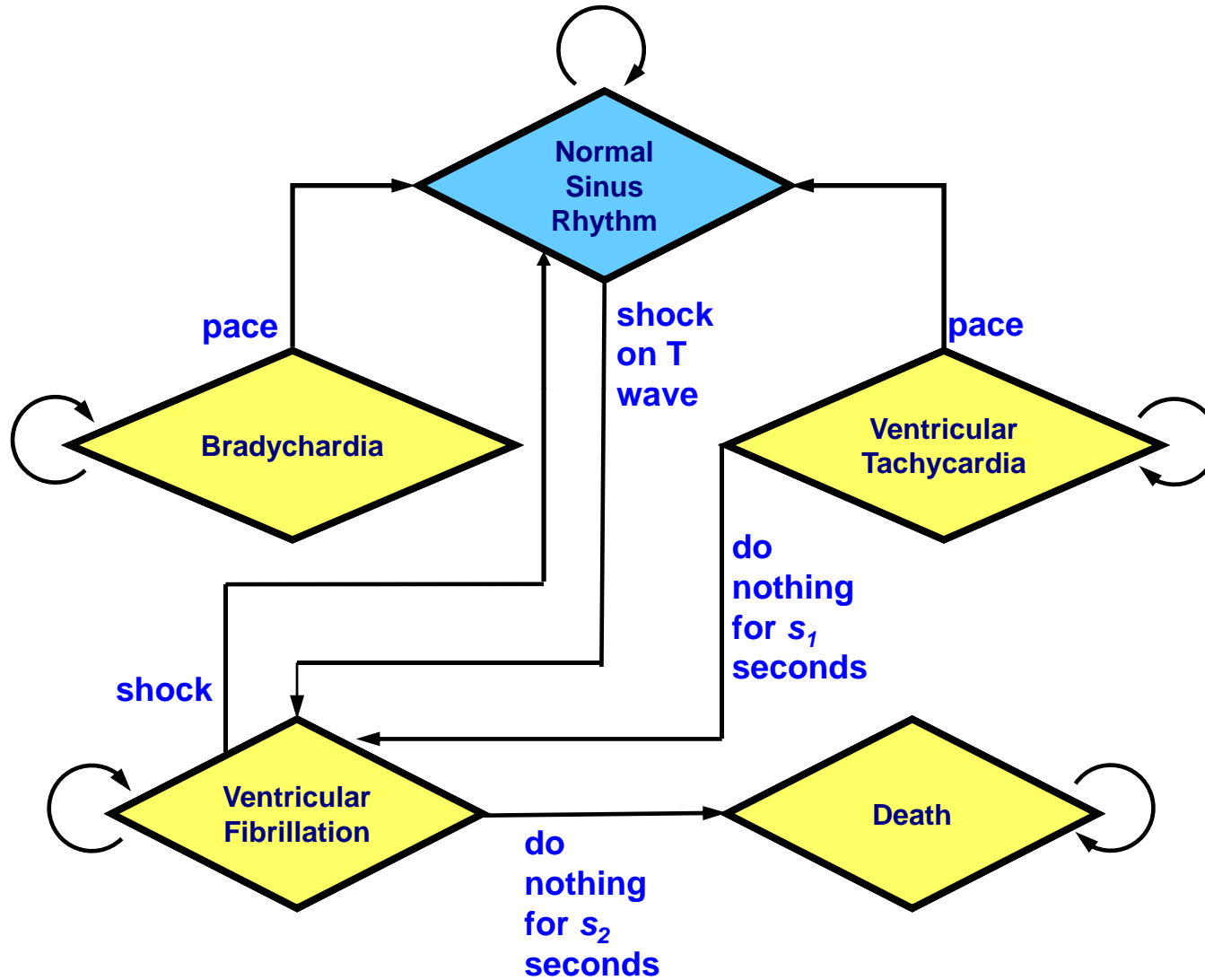


Vectorcardiogram



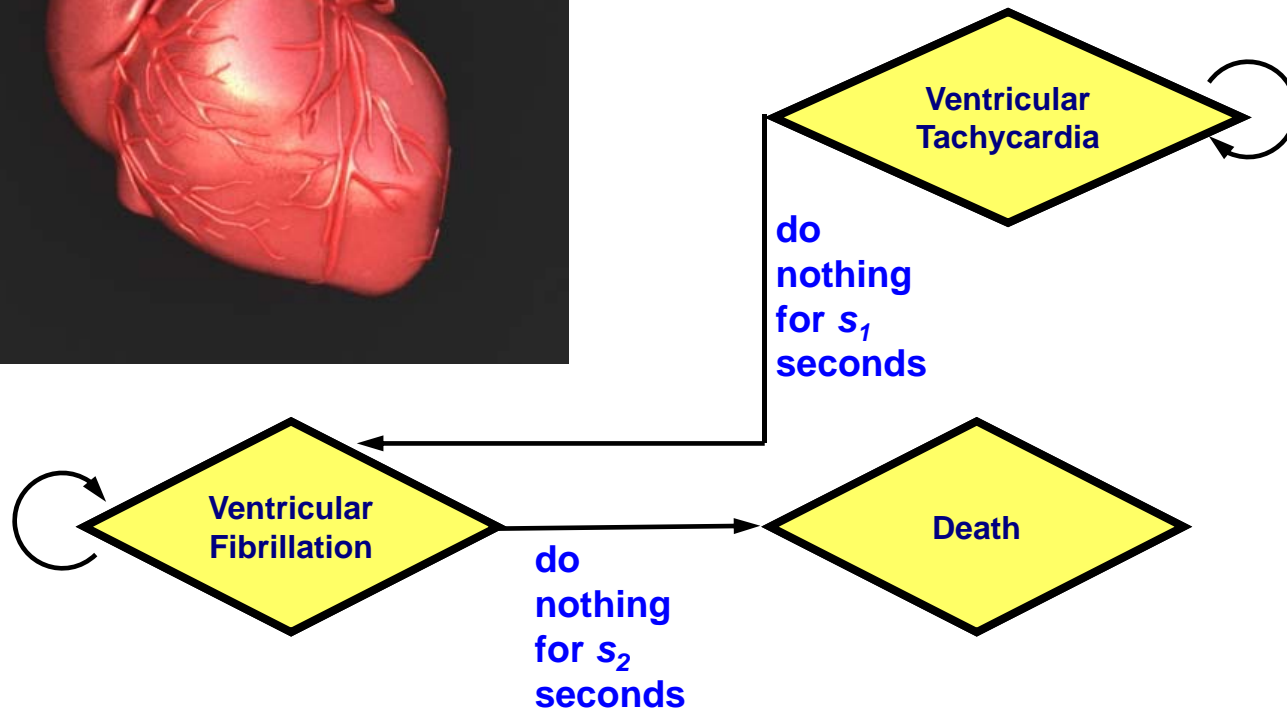
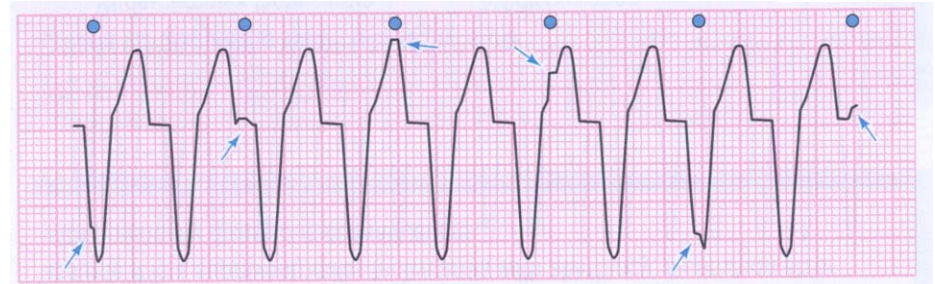
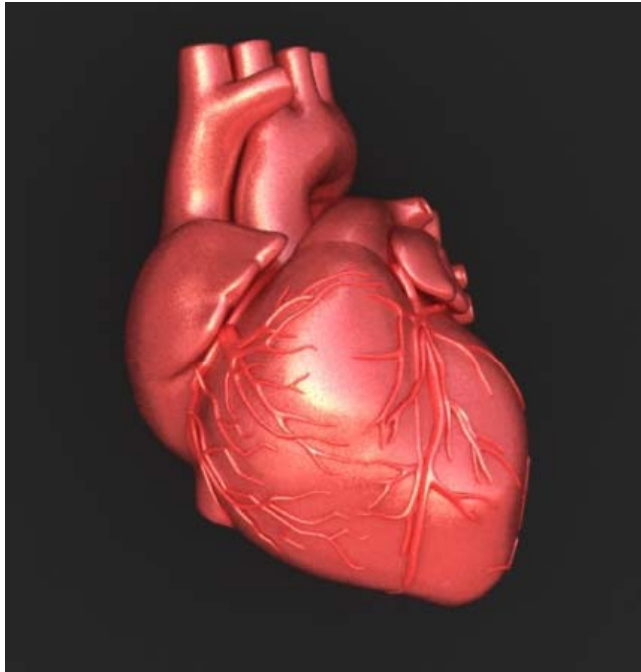
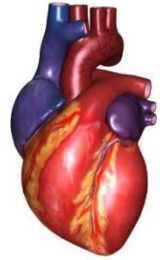


Closed Loop System



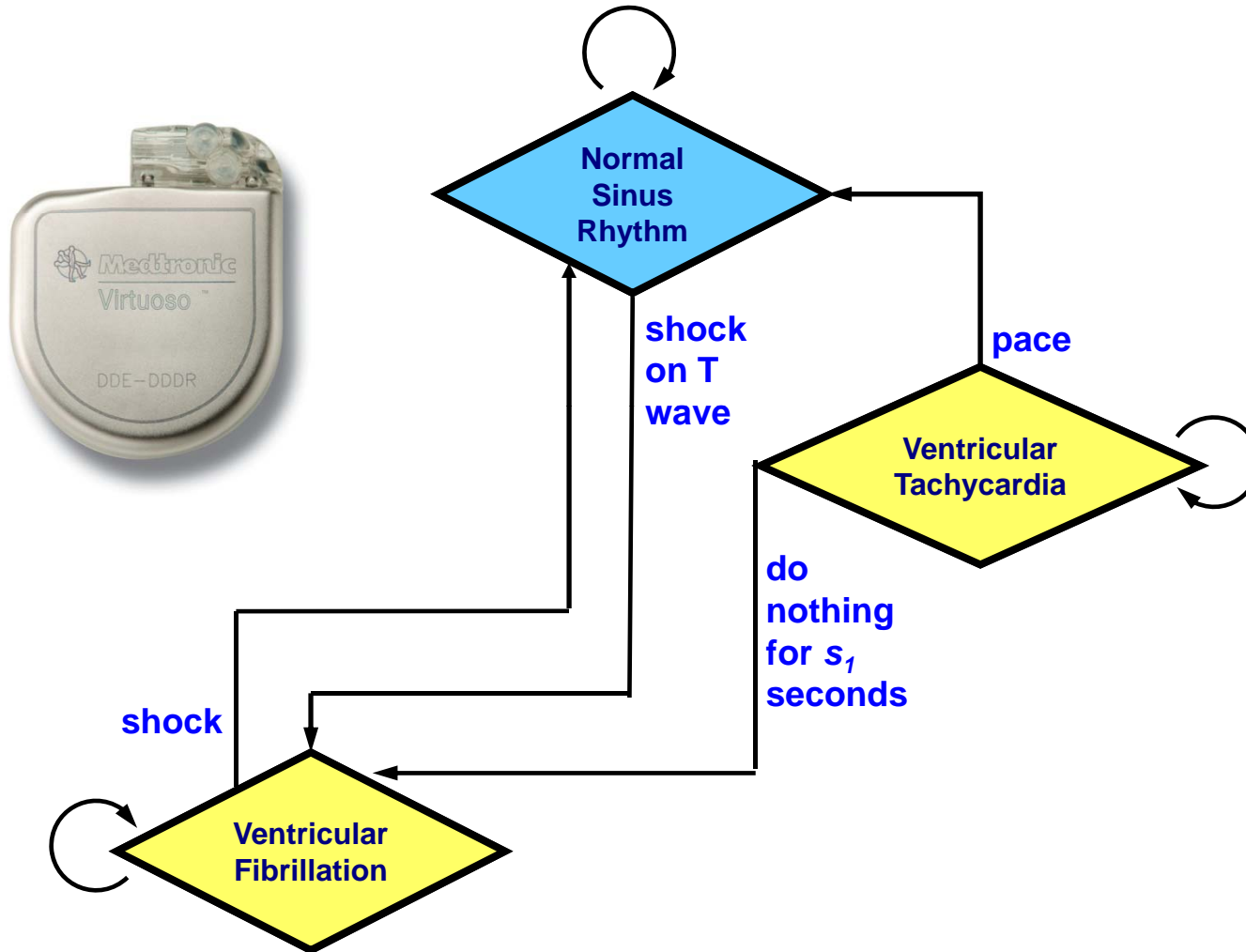


Open Loop Example

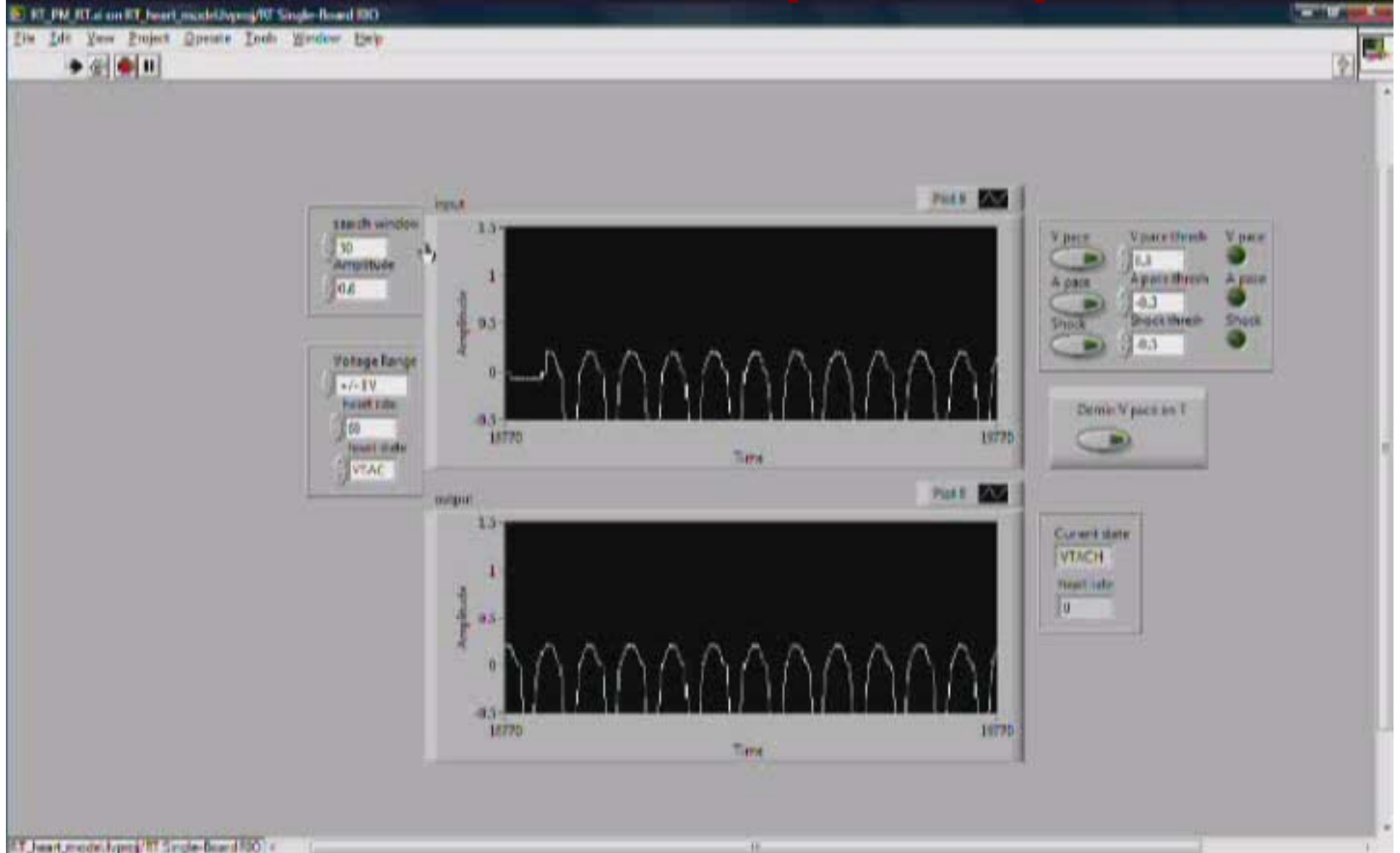




ICD Closed Loop Example

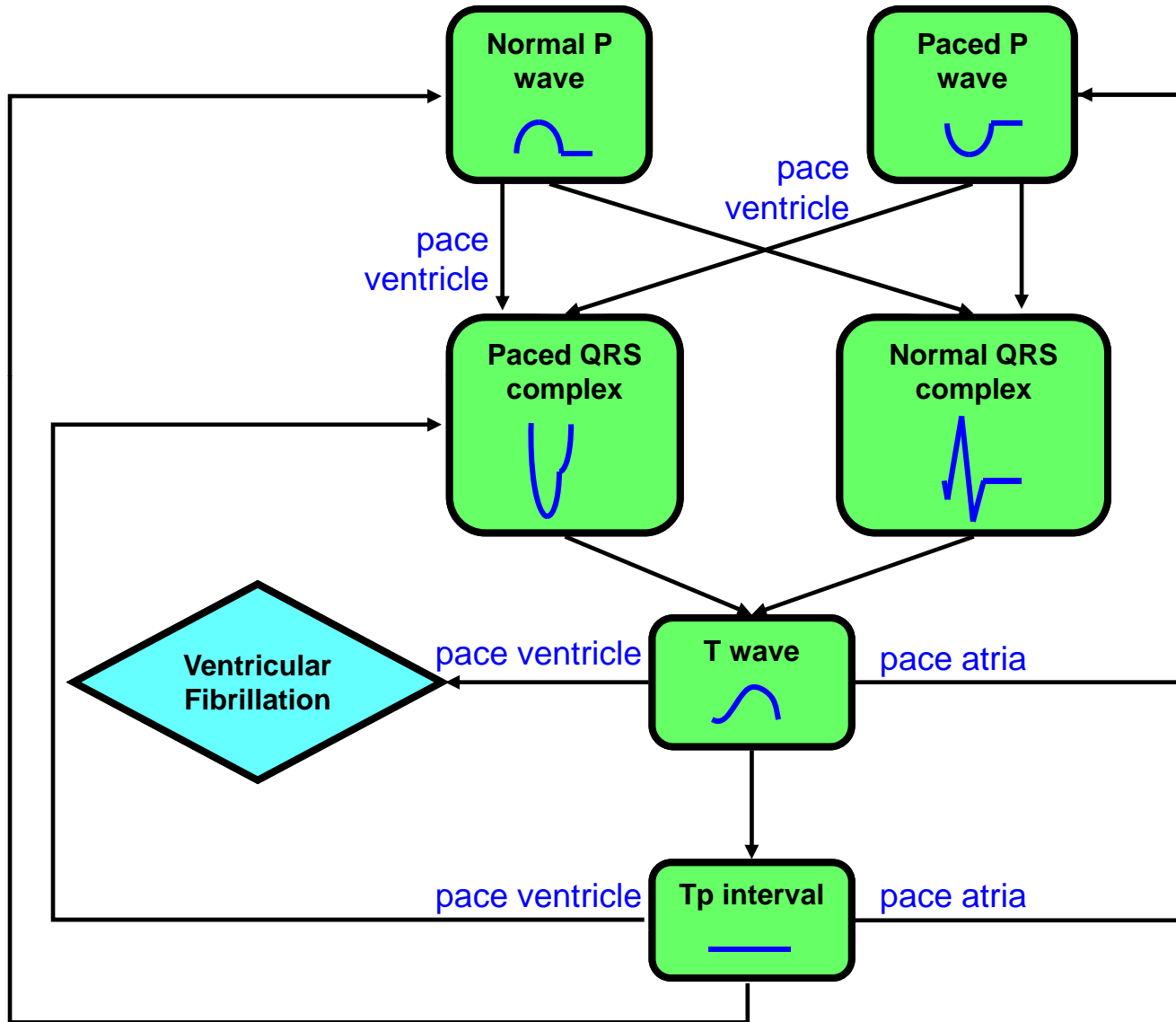


ICD Closed Loop Example

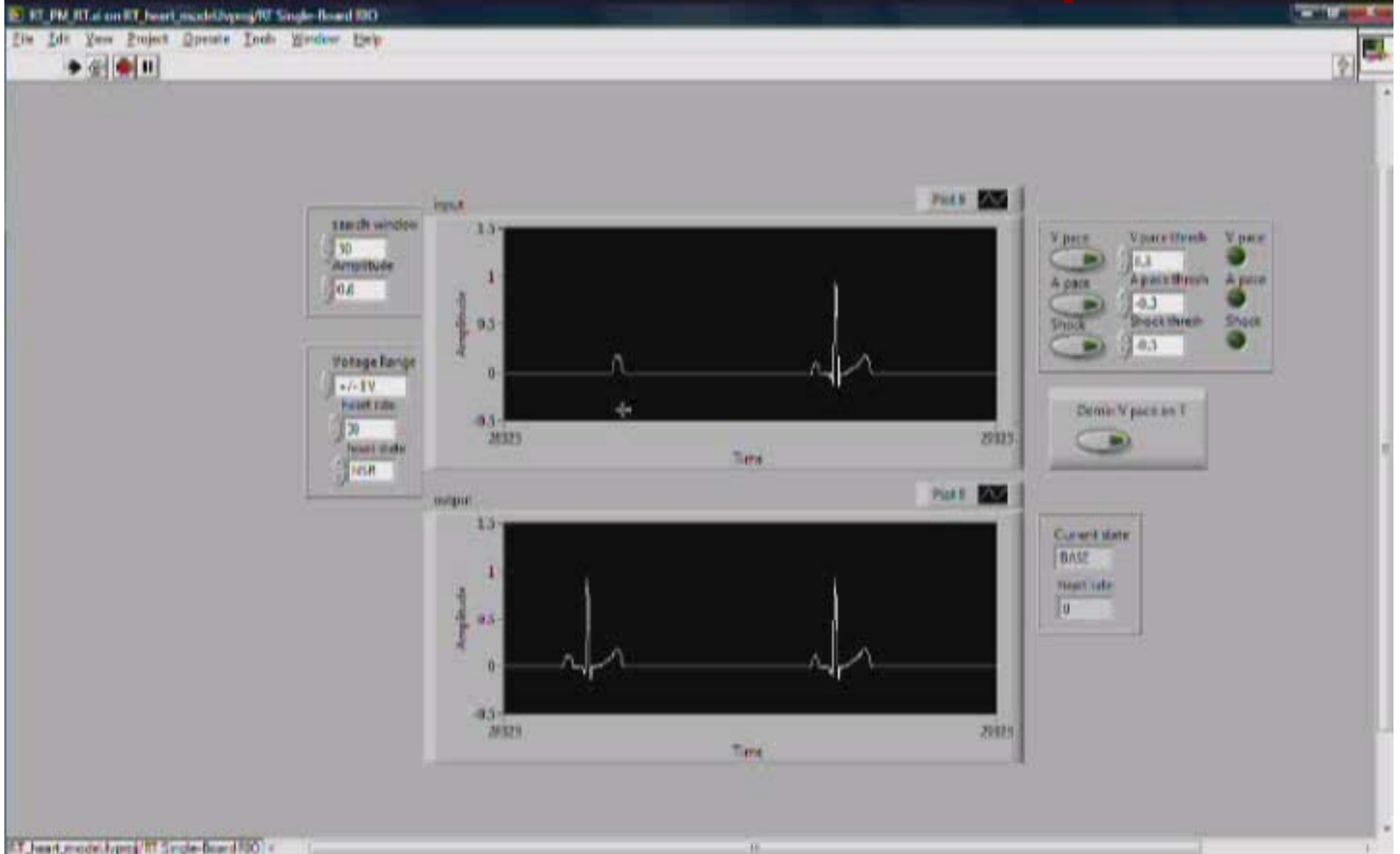




Heart Response to Pacemaker



Pacemaker Closed Loop





Medical Device Testing



- Model embedded in hardware
 - Direct connection to devices
- Validate and verify software
 - Reduce recalls
- Develop new software
 - Better discrimination algorithms





Conclusions



- + Created model that responds to device actuation
- + Model covers broad spectrum of arrhythmias
- Current model is too simple, only ECG
- Need to model intracardiac signals for implantable devices
- Need in depth model for proper device verification



Acknowledgements



- Prof. Rahul Mangharam
- Zhihou Jiang
- mLab members
- Dr. Ed Gerstenfeld
- Gorman Lab
- Jan Van der Spiegel
- SUNFEST staff
- NSF

QUESTIONS?

