Closed-Loop Formal Verification of ICDs using Cardiac Electrophysiological Models

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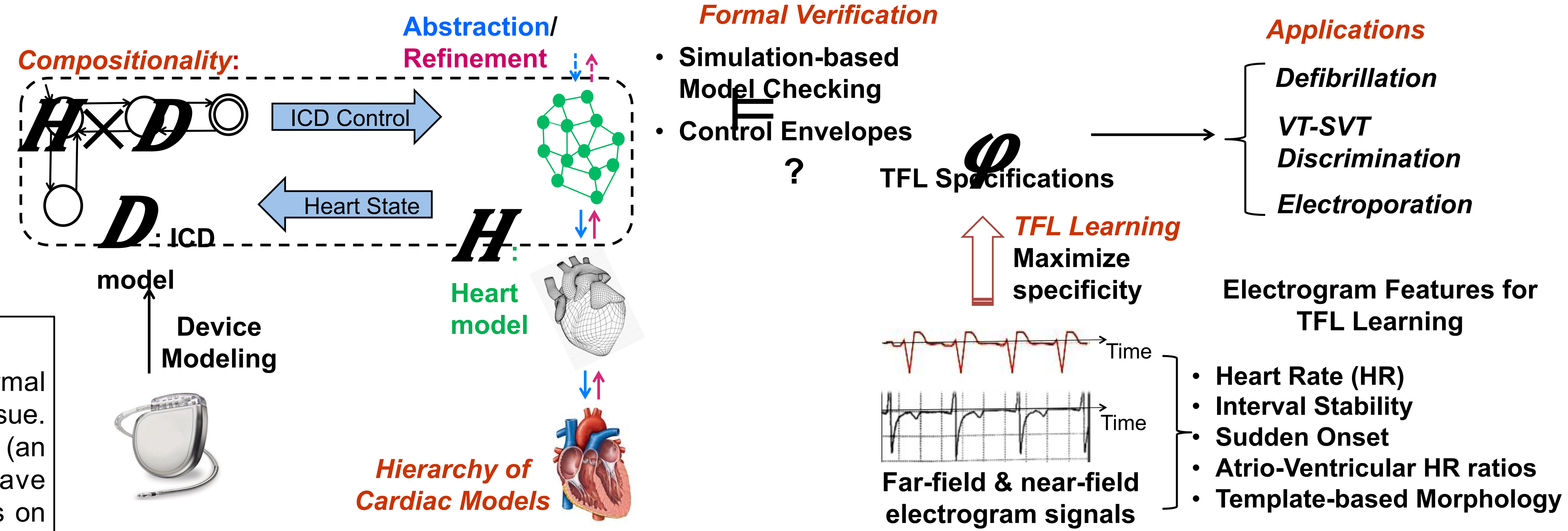
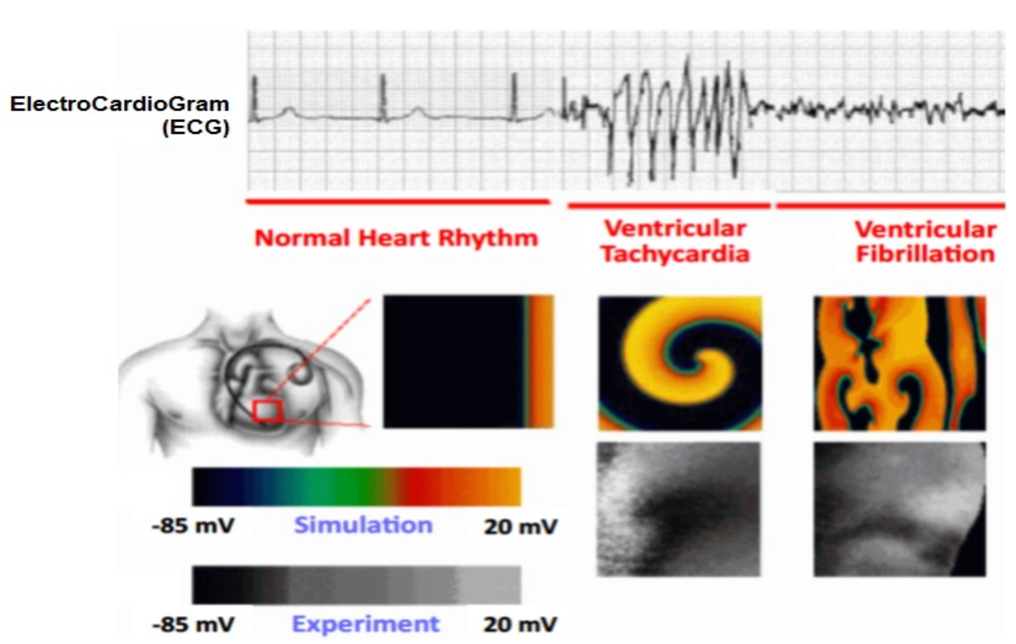
Closed-Loop Verification Framework for ICDs.



MOTIVATION

Cardiac arrhythmias are characterized by abnormal dynamics during the activation of excitable cardiac tissue. The figure below shows how ventricular tachycardia (an arrhythmic behavior characterized by spiral wave dynamics which appear as fast, quasi-periodic signals on the electrocardiogram) can deteriorate into ventricular fibrillation—a dangerous chaotic regime characterized by the loss of spatial correlation in the contractile dynamics of the heart. While in this state, the heart's ability to pump blood is severely degraded and death usually follows within minutes unless corrective measures are taken.



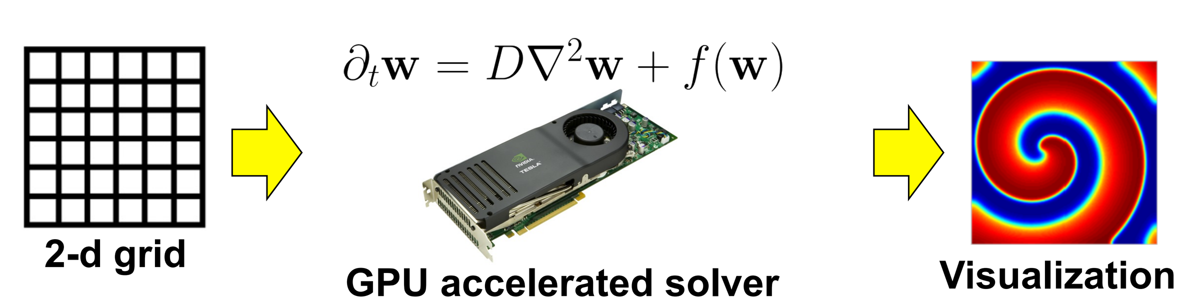
Implantable Cardioverter Defibrillators (ICDs) have evolved into complex Cyber-Physical Systems (CPSs) that use sophisticated hardware and embedded software to diagnose and terminate arrhythmias. Despite numerous advancements, inappropriate shock treatment due to sensing errors or arrhythmia misdetection in the electrogram signal continues to remains a safety concern.

PROJECT SUMMARY

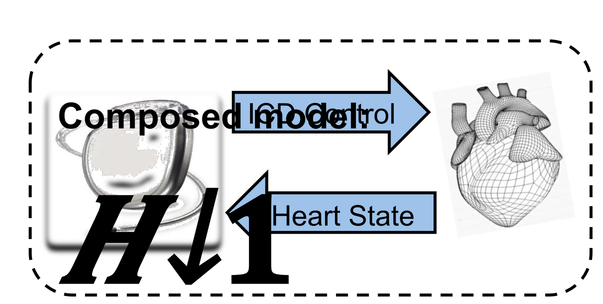
The National Science Foundation (NSF)/Food & Drug Administration (FDA) Scholar-In-Residence (SIR) at FDA project will address this problem by developing a model-based framework for formal verification of ICDs. Formal verification techniques, such as simulation-based model checking & reachability analysis, will be applied to high-fidelity cardiac electrophysiological models that integrate the electrical excitation induced by the ICD's control software. Safety requirements pertaining to common ICD problems, such as inappropriate shocking & VT/Supra-VT discrimination, will be specified using a Time-Frequency Logic (TFL) and automatically verified.

HEART MODELING

- RADIANT (caRdiAc DynamIc ANalysis suiTe) is an in-house, GPU-powered software package that was developed to simulate and analyze differential equations-based models (DEMs) of cardiac tissue.

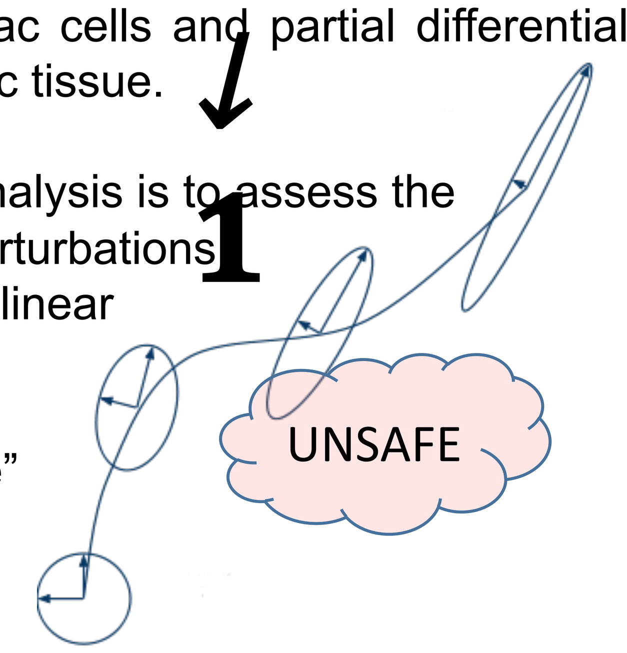


- Our simulations can be leveraged for the Verification and Validation of ICDs by creating a closed-loop model that connects DEMs of cardiac tissue to ICD-control software:

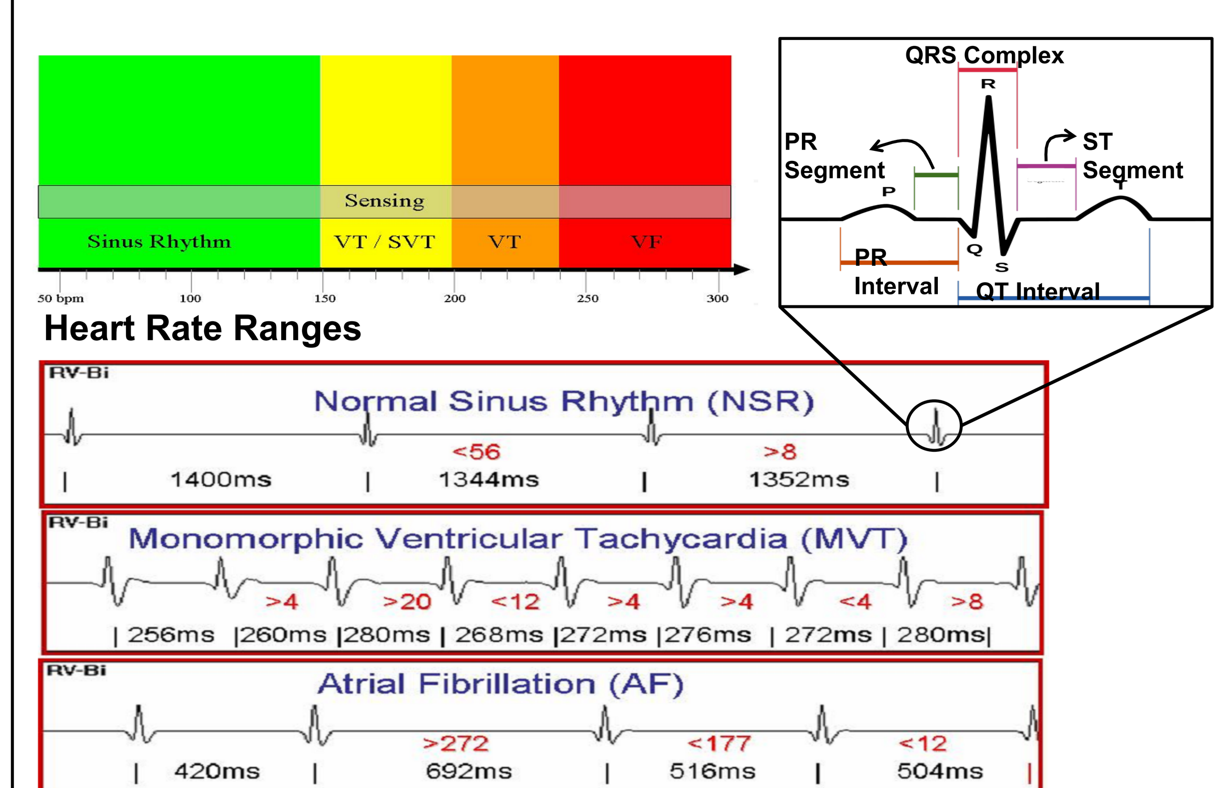


REACHABILITY ANALYSIS

- We are currently investigating the application of reachability analysis to nonlinear ordinary differential equation models of cardiac cells and partial differential equation models of cardiac tissue.
- The goal of reachability analysis is to assess the time evolution of small perturbations around trajectories of nonlinear systems to see if they could bring the system into a pre-defined "unsafe" subset of the state space.



ICD MODEL



Using temporal and frequency-domain aspects of electrograms for specifying VT-SVT discrimination.

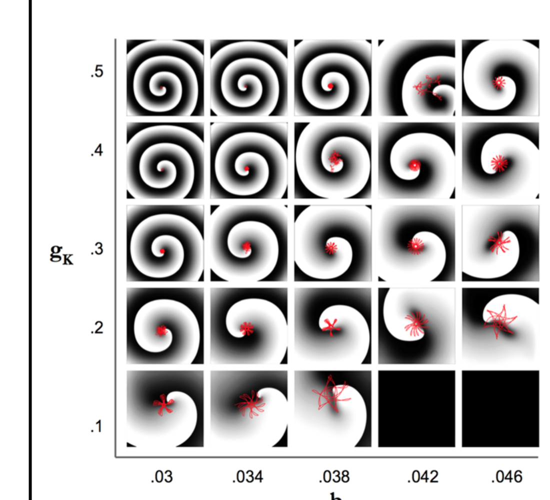
TFL [3] will be used to specify VT-SVT discrimination based on the following features of electrograms:

1. *Heart Rate*: inverse relationship with cycle length, the time interval between two consecutive R-peaks of the periodic electrogram.
2. *Stability*: variability in cycle lengths.
3. *Sudden Onset criterion*: compares the R-R interval to mean values & measures changes in the cycle lengths.
4. *QRS Complex Morphology*: compares the shape of the QRS complex to nominal patterns.
5. *Atrio-Ventricular Heart-Rate Ratios*: the ratio between the measured heart rates from the atria & the ventricles.
6. *Dominant Frequency*: efficacy of defibrillation depends on the Fourier transform of the electrograms.

EDUCATION & OUTREACH

- High school student mentoring

Two high school students from Soyoset, NY have been investigating spiral wave stability in a new cardiac cell model developed at the FDA. The results of this project (summarized in the figure below) were submitted to Intel and Siemens for their student research competitions.



A "flower garden" summarizes the dynamics of a single spiral wave as Two model parameters are varied. The spiral tips, shown in red, are used to classify the dynamics as: rigid rotation, Meander and hyper-meander. These dynamics are an important indicator of spiral wave breakup which, physiolgically, represents the transition from tachycardia to fibrillation.

- Seminar Series at FDA

Monthly seminars in numerical methods, nonlinear dynamics, high performance computing and physics will continue to be provided for the postdoctoral fellows, graduate students and research staff at FDA.

CONCLUSIONS

The project will undertake several problems that are fundamental to CPS theory & deliver cross-cutting tools that can be applied to multiple CPS-based domains. The underlying goal of reducing inappropriate shocks in ICDs will help to significantly improve the patient's quality of life while taking an important step towards the development of more reliable and efficient validation and verification techniques.

ACKNOWLEDGEMENTS

We thank NSF for the NSF/FDA SIR postdoctoral fellowship grant (#1445770).

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