Algorithmic Approach for the Design and Analysis of High-Confidence Medical Device Systems

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POSITION PAPER

Since the first cardic pacemaker was successfully deployed fifty years ago, an astonishing number of medical device systems have been developed and implanted in human bodies for helping patients with many kinds of ailments. In particular, neurostimulators have been used extensively for alleviating symptons in many illnesses by emitting brusts of low-voltage electrical signals in various parts of the human body. As neurosimulators get even smaller and their microchips more powerful, these devices can be injected almost everywhere in the body to generate highly complicated microshocks. The computational processes performed on the microchips tightly interact with the physical processes in the body. As a consequence, the interaction between the computational processes become an integral part of the system dynamics.

The multi-disciplinary research field of *hybrid systems* [1], [2], [3], [4] has emerged over the last decade and lies at the interface of computer science, control engineering and applied mathematics. In [5], [6], hybrid systems are defined as systems built from atomic discrete components and continuous components by parallel and serial composition, arbitrarily nested. Components in such a model are entities capable of performing some computation and the mechanism by which components interact is defined formally by the model of computation [7]. The hybrid phenomena captured by such mathematical models is manifested in a great diversity of complex engineering applications because the dynamical interactions between discrete and continuous components can be well captured in a unified modeling framework. There has been a large and growing body of work on formal methods for hybrid systems. The research discipline of hybrid systems provides a theoretical foundation for the modeling, analysis, and design of high-confidence medical device systems.

Symbolic methods[8] can be developed for the algorithmic analysis of hybrid systems[9]. These methods directly explore the infinite state space by using Boolean operations on state sets and the reachable set operations. The common notions and operations in these symbolic methods enables us to construct symbolic algorithms without considering details of implementations related to computational methods. We have developed a platform called ReachLab[10], which can be used to construct symbolic algorithms graphically, using the ReachLab library. They can then be computed by adopting some computational methods, such as d/dt [11] and the Level Set toolbox [12]. While d/dt can only handle affine continuous dynamics, the Level Set toolbox, which is based on the level set methods [13], [14], can handle nonlinear dynamics.

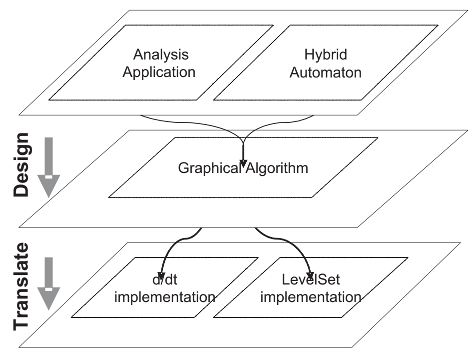

Fig. 1. Different layers of ReachLab platform. The application and corresponding hybrid automaton lies in the top layer. The middle layer is the library, which is used to model symbolic algorithms graphically. The library components are abstractions of the operations for analysis that are common in all supported computational kernels. Along with the analysis operations, the library also provides data structures, control flow entities, numerical operations, and Boolean operations. The bottom layer contains the supported computational kernels. Design is a process from top to middle layer, while translation allows mapping from middle to bottom layer

In [10], we have developed algorithms for estimating regions of attractions and invariant sets for continuous dynamical systems. Fig. 2 shows an example which uses the Vanderpol Equation [15] to demonstrate how algorithm can also be used to estimate the shape of the limit cycle. The Vanderpol Equation is used to model cardiac oscillation. In this example, it can be shown that there exist an attractive limit cycle and an equilibrium point inside the limit cycle. By negating the vector field of the Vanderpol Equation, the

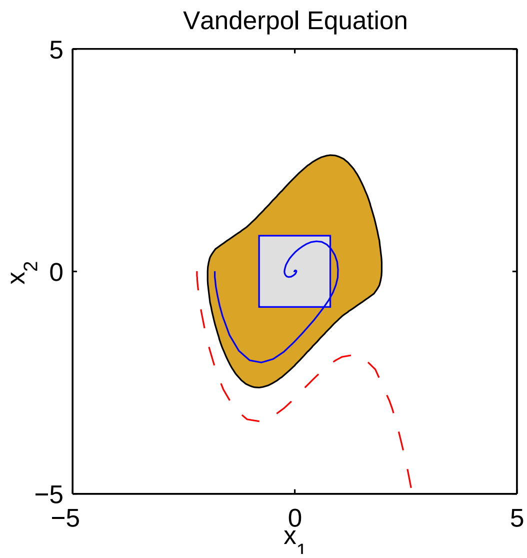

Fig. 2. An algorithm developed for estimating the shape of the limit cycle specified by the Vanderpol Equation. The dark region gives an estimate of the shape of the limit cycle.

limit cycle becomes repulsive instead of attractive. Then, by applying our algorithm, the shape of the limit cycle can be estimated, as the dark region shown in the figure. The dynamics in this example is defined by the ODE $\dot{x}_1 = -x_2$, and $\dot{x}_2 = -(x_2(1 - x_1^2) - x_1)$. The algorithms developed for continuous dynamical systems can be naturally extended to hybrid systems.

The intellectual merit of this work is threefold. First, it will advance the scientific understanding the modeling of medical device systems by using hybrid system models. Second, it will enable formal approach for the analysis of medical device systems by developing effective and efficient algorithms. Finally, it will evaluate the research results using software tools and experimental studies that can impact the development of embedded system design technologies for high-confidence medical device systems.

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