Component-Based Medical and Assistive Devices and Systems [+]

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1. Introduction

This paper discusses foundation for component-based design and integration, development and quality assurance, and certification of medical devices and systems. In addition to *medical devices* used in hospitals and clinics by professionals, we also need to be concerned with *assistive devices*, which are used by naïve users in and out of homes. Examples include medicine dispensers that can help to ensure correctness and enforce compliance of medication schedules, and monitors that can record and process vital-sign signals, detect irregularities, and send notifications. The division between assistive and medical devices is often blurry and future medical care and health delivery system will contain both.

The paper first discusses needed information technologies (IT) and sciences for each of the topics listed above. The roadmap at end of the paper suggests a plan to acquire them.

2. Foundation for Integration

Medical and assistive devices must be dependable: A dependable device works as intended, is highly available even when not well maintained, and when it fails or is misused, does no harm. Such devices also should be customizable, easy to use, upgrade and maintain. A time-tested way to build diverse systems with these desirable attributes at low cost is through componentization and reuse: building devices and systems by integrating configurable and evolvable components in a systematic way. Corner stones of component-based design and construction of medical devices include references models and associated standards to guide componentization, framework for system integration, and techniques for verification and validation of component-based design and implementation. We need research in these directions.

Models, Architectures and Standards Reference models and architectures of medical devices and systems are essential for the definition and standardization of components, interfaces and integration framework. Reference architecture (e.g., ones in [1, 2]) of a class of medical devices supports exploration of alternatives in partitioning and integration. It is an underpinning of any component-based development environment which offers libraries of components, integration platform and middleware, tools, user scenarios and benchmark workloads with which we can evaluate tradeoffs and carry out system integration, quality assurance and certification. Some reference models and accompanied standards have already emerged. (Examples include patient

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[+] The authors are members of the SISARL (Sensor Information Systems for Active Retirees and Assisted Living) project. The project focuses on enabling technologies for component-based design, implementation, verification and testing of diverse families of high-quality consumer and assistive devices and services for the elderly.

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model, virtual medical device and virtual vital sign monitor that underlie IEEE 1073 Standard for Medical Device Communications.) Most of them focus on low-level functions, while comprehensive models for all functionalities of devices and systems are needed.

Integration Technology Integration technology has made great strides for many applications. As an example, today's Enterprise Application Integration (EAI) technology enables enterprises to integrate diverse applications and systems and to model and automate their business processes. (EAI should be applicable to integration of many medical and health information applications and systems.) In contrast, integration technology for high confidence embedded systems has been moving at a snail pace; by and large, system integration remains ad hoc, costly and error prone. Much needed are principles, models, and tools for characterizing and simulating embedded components and their interactions for integration purposes. Integration of time-critical systems is further complicated by the fact that resource contentions among components can cause unpredictable timing behavior and make validation impossible or difficult. Although literature offers solutions, common platforms do not yet support them.

Compositional Techniques for Verification and Validation Advantages of component-based approach are much negated if verification and validation require that all components be verified and validated together based on complete information of design and implementation of all components. We need compositional verification techniques that allow the overall design be verified by parts and test architectures that decompose system validation to component validation as much as possible. Feasibility of these techniques is unlikely unless design and implementation are constrained to some degree. A challenge is to find the right tradeoffs between the cost of verification and validation and merits along other dimensions.

3. High Confidence Medical Device Software Development and Quality Assurance

Recent years have ushered in great improvements in software development and quality assurance processes and tools. There are now many good platforms and IDE (Integrated Development Environments) suitable for medical devices and systems. Increasingly, manufacturers world wide have adopted tools (e.g., those offered by the Capability Maturity Model Integration (CMMI) project) to help them improve, assess, and sustain the quality of their products, as well as their engineering, management, and quality assurance processes. No doubt, research on software and system engineering tools and processes is still desirable, but advances in them are not sufficient.

Like a sound foundation for integration, better tools and environments can help us meet the challenges in *building systems right*. An equally important challenge is *to build the right system*, as pointed out by Drs. Wears and Berg in their March 2005 *Journal AMA* article "Computer Technology Still Waiting for Godot". The authors suggest that the root cause of errors such as the medication errors introduced by physician order entry systems described in [3] is that "the pattern of (IT) use is not tailored to the workers and their environment". There is no choice for us but to adopt the user-centered approach, which calls for consideration of users (including care givers, patients and service personals) throughout requirement acquisition, design and evaluation. Research needed for user-centered design and quality assurance includes the creation of a library of user scenarios, user models and their environments in the context of medical devices and systems based on real data. We also need standards similar to ISO13407 to guide user-centered derivation of requirements and design and evaluation against the requirements.

4. Medical Device Software Certification

A quick glance may lead to the conclusion that medical devices can be certified using existing

technologies, including techniques that are to certificate other safety-critical systems (e.g., avionics) and techniques (e.g., RMA) that make real-time properties of non-deterministic applications running on commodity platforms certifiable [4]. Common assumptions underlining these techniques are that system is closed and that relatively high cost of certification is acceptable. These assumptions are not valid for most medical devices and all assistive devices. Incremental techniques will not only enable low-cost certification of open devices and systems at initial deployment, but are also needed for certification of patches and upgrades. Challenges in incremental certification coincide with those outlined in Section 1. Indeed, compositional verification and validation techniques can serve as the basis of incremental certification. A system designed for compositional verification and validation will be incrementally certifiable.

The difficulties in certifying adaptive systems cannot be overcome without rigorous science on observability (testability), controllability, and stability of the underlying adaptive algorithms. In particular, instabilities that can occur and cause fatal failures with non-negligible probability may remain undetected despite thorough testing, especially when the tests are not tailored to the adaptive system. It is reasonable to require as a part of certification rigorous proofs of (i) that the system will adapt as intended and always within an envelope of safety, at least in principle, and (ii) that the certification procedure for that system will indeed indicate with high confidence whether the system works according to its design principles.

5. A Possible Roadmap

The research needs outlined separately in previous sections are interrelated. The roadmap below summarizes work to be done to meet them.

First Five Years Researchers, developers, users and other stake holders of medical devices and systems need mobilize from the start. Together they need to create repositories of (i) extensible user scenarios and models and (ii) reference models of different types of medical devices and systems. The artifacts will provide context to guide and focus efforts on the foundation of component-based design and system integration and technologies for incremental verification, validation and certification. Good standards, including user interface standards, take time to develop, and their development should have high priority in the first five years. For maximum practical impact, we should fully develop a subset of ready-for-use techniques, tools and simulation models that work for important but simpler types of devices and systems, while we charter future courses of exploration in all fronts of research.

Second Five Years Ideally, the research during the first five years will provide a sound foundation for the design, development, evaluation and certification of a majority (e.g., 70-80%) of all medical devices and systems. The second five years can then be devoted to further solidify the foundation and to seek the missing science and technologies required for the remaining minority of devices and systems that are more challenging to build and certify.

References

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[4] *Proceedings of IEEE RTSS and RTAS* in years 1987 - 2004