Position Paper:
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Introduction

Modern safety-critical medical devices are complex systems where electronics and system software play an ever increasing role. This position paper focuses on two research topics crucial to developing high integrity medical device systems (MDS): (1) *Distributed control and sensing*, and (2) *patient modeling and simulation.* An ongoing research project on image-guided radiation therapy at the Massachusetts General Hospital will motivate some of the research challenges outlined in this paper. This project aims to improve the effectiveness of radiotherapy via precise tumor localization and radiation-beam delivery during treatment. Various techniques for image tracking, dynamic targeting, and adaptive therapy are being developed.

Figure 1 shows the hardware setup and functional schematic of the Integrated Radiotherapy Imaging System (IRIS)—an imaging and therapy system to quickly and precisely set up patients, and localize and treat tumors with inter- and intra-fraction motion [1]. Multiple sensors—CCD cameras and silicon flat panels—mounted on the gantry of a medical linear accelerator provide real-time images of the tumor. The IRIS system determines tumor position at any given time instant and adjusts the treatment-beam position appropriately. It integrates major imaging functions including radiograph-based patient positioning, cone-beam CT, and real-time tumor tracking.

IRIS is typical of a networked MDS having the following characteristics. (1) *Distributed control*: A networked MDS involving distributed sensing and control functions is realized as a real-time system comprising sensors, computers, and actuators interacting via a communication network. In IRIS, for example, diverse sensors image the patient while multiple computers collaborate to perform major tumor tracking and motion prediction functions. Imaging data is exchanged between computers over a high-bandwidth network. (2) *In-house development*: Many important devices are developed by research hospitals or small companies. Components-of-the-shelf (COTS) and other proprietary hardware (software) components are typically used to reduce development effort and cost. (3) *Quality-of-service (QoS) requirements*: The applications executed by the MDS have stringent QoS constraints, including timing and safety requirements. (4) *Testing complexity*: Detailed and application-specific patient modeling and simulation is needed for MDS functional testing, aimed at validating and improving its performance.

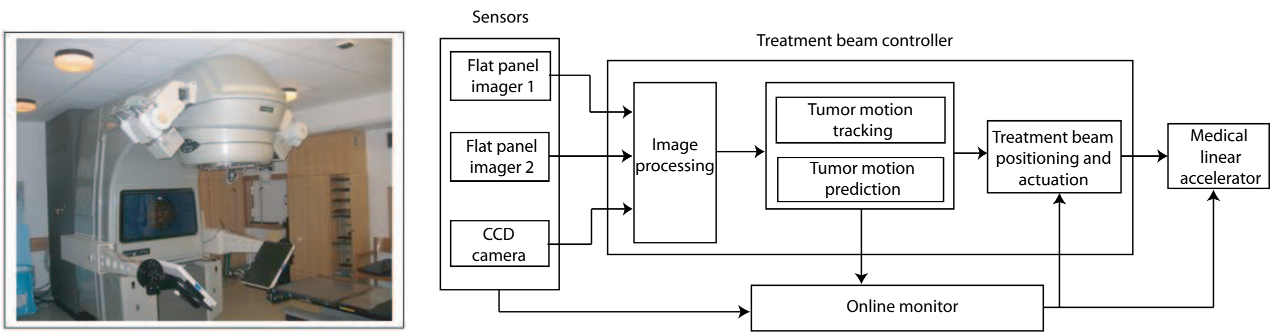

Figure 1: The IRIS hardware and its functional schematic

Distributed Control and Sensing for Networked MDS

The following research challenges and needs must be addressed to develop high confidence networked MDS involving distributed sensing and control.

On-line verification. COTS hardware (software) such as commercial microprocessors (operating systems) are typically used during in-house MDS development where some third-party components are provided in an incompletely specified form to protect proprietary rights; for example, vendors may not reveal low-level design and implementation details. Since these details largely determine the system's failure modes, such systems can be difficult to test and verify. Furthermore, these components may contain functions not used by the MDS, but are left in place by their designers. The limited knowledge about such components introduces an element of nondeterminism into MDS design and operation. Such nondeterminism can be at odds with safe MDS operation, which requires that it operate within a precisely controlled set of safe operating states.

Research need: The problems of monitoring a MDS in real time to ensure that its operation meets the prescribed objectives must be addressed. The on-line monitoring framework itself may be hierarchical in nature. For example, critical back-box components can be checked using corresponding behavioral models—perhaps generated via classical system identification techniques. High-level MDS behavior (e.g., tumor tracking error [2]) can also be monitored using appropriate application signals. Finally, the actuator itself must be independently monitored [3].

Network design considerations. Designers of a real-time distributed MDS must be able to quantify and analyze the impact of the underlying network architecture on control quality. This analysis can help determine feasibility of the design and provide guidelines for choosing the most suitable network system. For example, IRIS comprises multiple sensors, computers (running Windows 2000) and actuators, exchanging messages via an ethernet connection. Other peripheral devices may also be connected to this network. The impact of timing uncertainty (or jitter)—during application execution and message transmission—on control performance must be analyzed. Furthermore, the (un)availability of other critical network services (e.g., synchronized clocks are needed to register images from multiple sensing sources), and their impact on performance must also be considered.

Research need: To enable fast prototyping and feasibility analysis, techniques and tools for theoretical analysis and simulation of a network-control system must be developed—focusing on the types of control problems encountered in typical MDS design. Sensitivity analysis to determine optimal control parameters is also needed.

Fault-tolerant control. An online monitoring framework detects MDS component failures, possibly shutting them down. However, shutting down the MDS completely for time-consuming repairs after a component failure may disrupt treatment plans for many patients. Therefore, the MDS must continue to operate under failure conditions while achieving acceptable control quality.

Research need: A high-availability MDS must be designed to offer a limited number of degraded treatment options. Designers must be able to analyze, in off-line fashion, the impact of system failures on MDS control and operation, and research is needed to develop such analysis tools. (As an example, theoretical studies have been performed on IRIS to determine how big the tracking error is when only one imaging system is used.) Also, detailed logging is needed during MDS operation to aid treatment verification and failure recovery.

Roadmap. Research must focus on developing analytical and simulation techniques to quickly determine the feasibility of a fault-tolerant networked MDS design in terms of its desired treatment goals. Of particular interest is to accurately characterize COTS-induced nondeterminism on control quality. Also, the extent to which online monitors can diagnose MDS failures and support fault tolerance must be examined. Finally, the difficult task of hardware-software design error monitoring—in effect, on-line design verification—should be considered.

Patient Modeling and Simulation

Patient modeling directly impacts MDS design, and offers opportunities for new treatment modalities. Of particular interest are applications to interventional treatment and quality assurance, where the patient can be considered a model providing an external disturbance to the control system.

Mathematical models of human geometry. In 1994, the National Library of Medicine established the gold standard in human geometry with the release of the visible human project. This work has revolutionized patient modeling by providing researchers around the world access to high quality data. However, we recognize that two healthy humans are insufficient to capture the wide variety of natural variation seen in a hospital. Therefore, high fidelity geometric models that can be quickly adapted to a wide patient population are required.

Research need: The following problems must be addressed: (1) High-quality data is both difficult and expensive to get, and therefore, researchers are often unwilling to share data. (2) Most mathematical models expressive enough to capture a wide patient population have numerous parameters and are unwieldy, leading to poor acceptance.

On-line model adaptation. During an interventional treatment, sensors monitor the patient to ensure that the treatment is proceeding according to plan. For example, IRIS monitors patient geometry using video or fluoroscopic imaging during treatment. If the patient has moved out of position, treatment must be temporarily stopped and the patient realigned. Because of advances in applied mathematics and computer processing speeds, it is possible estimate organ deformation parameters to some extent. However, this information is currently not used to modify radiation treatments because they are difficult to visualize and verify.

Research need: There is a need for simple, yet expressive models of organ deformation and motion. These models should allow for on-line adaptation, be easy to visualize, verify, and control interactively.

High fidelity physical phantoms. Physical devices (or phantoms) are needed during three key stages in the clinical implementation of complex MDS: (1) System integration, performed by the industrial partner to verify proper design. (2) System validation, performed by the hospital to ensure that the MDS operates correctly and communicates with other devices. (3) Procedure rehearsal, performed by the clinical staff to prepare for complex procedures or enact changes in operation protocol.

Research need: Most phantoms concentrate on a single important physical attribute; for example, imaging, dosimetry, or surgical phantoms. However, phantoms having multiple properties are desirable. In image-guided therapy, phantom organs must deform in a plausible manner, and have plausible imaging and dosimetric properties.

Roadmap. For mathematical modeling and model adaptation, research efforts should focus on simple, knowledge-based approaches to patient modeling. Simplicity improves the transparency, robustness, and ease of use for most software systems, and ultimately lowers cost. Simple models can be made more expressive via knowledge-based approaches that capture human physiology and intended interventional use.

References

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Author Biographies

Greg Sharp is an Assistant Radiation Physicist in the department of Radiation Oncology at Massachusetts General Hospital (MGH), and Instructor on the faculty of Harvard Medical School. In 2002, he received his PhD in computer science and engineering from the University of Michigan, specializing in computer vision. Prior to graduate school, Dr. Sharp designed embedded software for various high speed I/O devices at IBM and Intergraph. He is currently the principle software architect of the IRIS project, a system for image-guided radiation therapy at MGH. His research interests include image and signal processing, medical device instrumentation, and patient modeling.

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