National Workshops on Medical Cyber-Physical Systems

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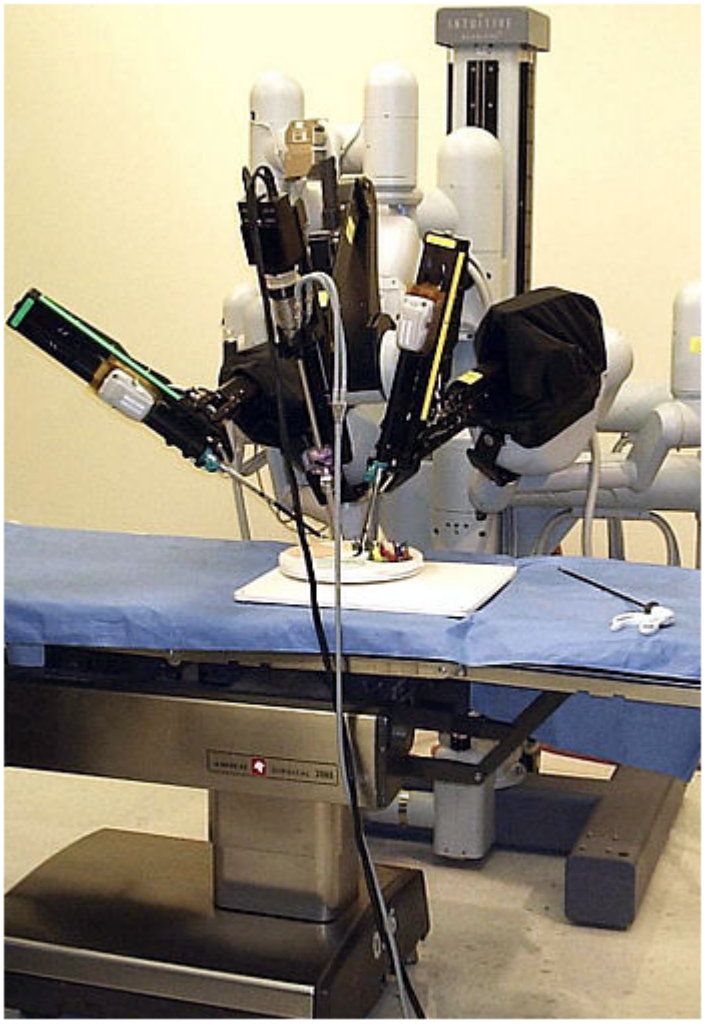


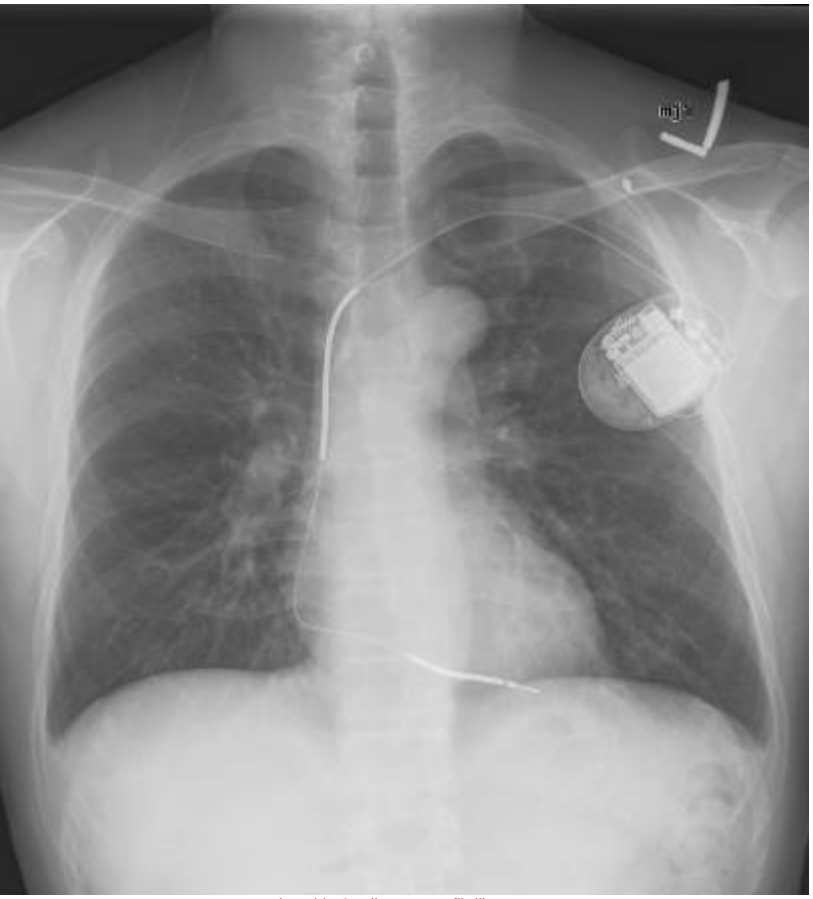
Patient-side cart of the da Vinci surgical system Photo credit: Nimur

The emerging discipline of cyber physical systems (CPS) seeks to harness progress in science and technology to enable innovation in engineering modern systems, by integrating principles and practice from physical modeling, dynamics and control, real-time embedded computing, computing architectures, networking and wireless communication, and certification and assurance technology. Opportunities for CPS-enabled innovation in medical device technology include, as examples, the introduction of coordinated interoperation of autonomous and adaptive devices, as well as new concepts for managing and operating medical physical systems using computation and control, miniaturized implantable smart

sensing and actuating platforms, energy harvesting, body area networks, programmable materials, and new fabrication approaches such as 3D printing.

The aim of the workshops is to bring together academic, clinical, and industry experts in technologies and processes to identify and explore new CPS manifestations in design methods and platforms that would encourage radical innovation in next generation diagnostic and therapeutic devices and their control, integration, and manufacturing. The overarching goal is to find safer, more effective, more capable, and more reliable solutions than with current approaches, and to consider solutions that will cross the kinds of domains indicated in the topic area examples below. By bringing together cutting-edge technologists with visionary clinicians and biomedical engineers, we hope to stimulate new perspectives and different ways of thinking that generate excitement and foster opportunities for collaboration. Emerging opportunities for innovative medical devices include new actuation modalities such as optical, ultrasound and thermal; new methods for device placement and drug delivery; new therapeutic interventions; and new technology approaches for managing device heterogeneity in interoperation and physical interaction.

Key objectives for the workshops include: (1) educating the CPS community about over-the-horizon medical technology needs and opportunities, and the medical device development community about emerging CPS technologies and capabilities; (2) encouraging investigators to think about CPS at the medical device design stage rather than as an afterthought; (3) envisioning how new CPS technology could influence new medical device capabilities and open up new device opportunities; and (4) providing FDA perspective on the pathway to integrate CPS technology and methods into medical technology to make devices more reliable and safe. The workshop is expected to develop a report by NITRD NCO that guides future science applications for CPS research technology.



Implantable Cardioverter Defibrillator
Chest X-ray Photo credit: Gregory
Marcus, MD, MAS, FACC

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Vision of devices that could exist in the future (in 5-10 years) - potential topic areas:

- What technologies are needed for future devices?
    - Energy scavengers and micro-powered devices
    - Micro-sized systems on a chip
        - Mixed fluid-sensor-actuator devices
    - Translational opportunities, e.g. systems, batteries, packaging, electromagnetic interference
        - Models of system components (sensors, actuators, computational)
    - Physiological models for heat transfer, miniaturization of ultrasound, artificial pancreas, device design and verification, etc.
        - Use of simulation (models) to assist in product development and validation
    - Behavioral attributes of device models
- What development pipeline / development processes are applicable or need to be developed?
    - What attributes will these processes produce to support safety and

effectiveness?

- What new technology opportunities should be focused on?
    - New technologies, devices, and concepts needed to make a difference
    - Current devices that could be improved (e.g. infusion pumps, pacemakers, ventilators, surgical or medical care robots)
    - Improved patient safety through data fusion, clinical decision support, and device control enabled by device integration: medical device interoperability
    - Distributed devices
    - Core technologies that can be broadly applied
- How do we assure safety and effectiveness, e.g. to meet regulatory requirements?
    - Risks/challenges, e.g. control issues and explicit hazard definition and mitigation, to enable safe systems of integrated medical devices
- How do we educate physical systems scientists in cyber physical systems concepts and practices?
- How do we frame medical device innovation, education, etc. for the future?

Medical Devices CPS Domains Health Care Manufacturing Robotics CPS Technologies Foundations Workshop Proceedings