

# Medical Device Interoperability

*The lack of interoperability between medical devices can lead to preventable medical errors and potentially serious inefficiencies that could otherwise be avoided.*



## Overview

From acute care clinical settings, to vital-sign monitoring, and devices that make telemedicine an accurate diagnostic and treatment discipline, medical devices are playing an ever-increasing role to transform healthcare delivery. These devices have the ability to capture critical medical data, available (perhaps) multiple times per second, on a per-patient basis. However, for the most part, they are unable to communicate with one another and offer almost no plug-and-play interoperability.

## Industry Need Addressed

Lack of reference implementations for existing device interface standards and unanswered questions regarding the safety and performance of networked systems-of-systems are among the challenges to achieving medical device interoperability.

## NIST Approach

In collaboration with experts from other federal agencies, industry, and academia, NIST researchers are currently working on efforts that promote standard-based medical device interoperability and communication.

- **Medical Device Interoperability Project** - NIST researchers in collaboration with the Massachusetts General Hospital and the Center for Integration of Medicine & Innovative Technology are working to achieve the vision of interoperability by conducting research in clinical requirements as outlined by the American Society for Testing and Materials (ASTM) F2761 standard. This standard specifies requirements and characteristics necessary for the safe integration of medical devices in operating rooms, emergency rooms and intensive care units. The research effort includes a gap analysis of the medical device communication standard ISO/IEEE 11073 versus use case scenarios outlined in the ASTM F2761 standard. NIST software engineers are also working with the ASTM F2761 Standards Committee to improve the functional architectures embodied in the standard, and with developers of reference implementations funded through National Institute of Health (NIH) grants. This work will result in testable prototypes and improved standards documents for use by industry to develop improved medical devices.
- **Medical Device Communication Project** - NIST researchers are collaborating with medical device vendors and domain experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise, as well as integration into the electronic health record. NIST is actively developing medical device communication test methodologies and tools to provide a key tool set needed to enable consistent and correct communication between medical devices, device-gateways, and across the healthcare enterprise. This work serves to provide standards-based and rigorous validation of medical device communication through conformance leading to interoperability. Rigorous testing is essential to achieve multi-vendor and enterprise-wide interoperability and must be predicated on sufficiently specified medical device and enterprise-communication standards. NIST is developing and advancing software test tools to support device communication in point-of-care and personal health settings. These tools are derived and implemented to meet medical device-level communication requirements defined in the ISO/IEEE 11073 Medical Device Communication (x73) family of standards and enterprise/electronic health record level defined in the Health Level 7 (HL7) messaging standard.

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## *Impact*

The result of these efforts will help the development of a standard-based interoperable framework that allows novel clinical solutions to be safely and efficiently incorporated. This will lead to:

- Fewer transcription errors and a richer set of information with which clinicians can manage their patients.
- Synchronization, safety interlocks and closed-loop device control for medical devices.
- New generation of medical sensors and actuators that can be integrated with the existing infrastructure as they become available.
- Easily deployable protocols and treatment solutions that are driven by what the healthcare providers need instead of what a technology manufacturer can supply.

For additional information, please visit <http://www.nist.gov/healthcare/emerging/deviceinteroperability.cfm>

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