



MEDICAL DEVICE
COMMUNICATIONS
INDUSTRY GROUP
A PROGRAM OF THE IEEE
INDUSTRY STANDARDS AND
TECHNOLOGY ORGANIZATION

ISO/IEEE 11073 Standards for Medical Device Communication

What are the IEEE 1073 standards?

IEEE 1073 standards enable communication between medical devices and external computer systems. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are to:

Provide real-time plug-and-play interoperability for patient-connected medical devices

And

Facilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments.

“Real-time” means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second. “Plug-and-play” means that all the clinician has to do is make the connection – the systems automatically detect, configure, and communicate without any other human interaction. “Efficient exchange of medical device data” means that information that is captured at the point-of-care (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support, and without needless loss of information.

The standards are especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc. They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced. There are four main partitions to the standards: (1) transports (e.g., cable connected or wireless); (2) general application services (e.g., polled vs. “event driven” services); (3) device data (including a nomenclature or terminology optimized for vital signs information representation, an object-oriented data model, and device specializations); and (4) internetworking and gateway standards (e.g., a gateway from IEEE 1073-based messaging and data representation to HL7 or DICOM).

What problems exist due to non-standardized medical device connectivity?

- Due to the complete absence of standards for these medical devices, (a) data is captured either manually or at considerable expense (using specialized equipment), or (b) it is not captured at all, which is most often the case.
- Manually captured data is labor intensive, recorded infrequently (e.g., written down hourly by a nurse clinician), and prone to human error.
- Use of expensive custom connectivity equipment (a) drives up the cost of health care delivery; (b) is only used for patients with the highest acuity; and (c) tends to lock health care providers into single companies or partnerships that provide “complete” information system solutions, making it difficult to choose best-of-breed technologies or the most cost effective systems.

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- Development and deployment of advanced care delivery systems are hindered. For example, systems that collect real-time data from multiple devices and use the information to detect patient safety problems (e.g., adverse drug events), or to quickly determine a patient's condition and automatically or with minimal clinician involvement optimally adjust a device's operation (e.g., drug concentration delivered to premature babies based on heart rate and blood pressure information).
- Since there is no standardization in this area, even when similar devices do provide communications, there is no consistency in the information and services that are provided, thus inhibiting the development of advanced care delivery systems or even comprehensive patient health records.
- In short: Medical device communication standards help patients become healthier quicker and at a lower health care cost.

Why IEEE 1073 standards?

- These are *the only standards addressing this area of connectivity*
- They provide a complete solution for medical device connectivity, starting at the physical cable and connector up through the abstract representation of information and the services used for its management and exchange.¹
- Internationally harmonized – The IEEE 1073 standards have been developed with a high level of international participation. They are also being “fast tracked” as International Standards Organization (ISO) standards through ISO TC215 Health Informatics, specifically as the ISO 11073 series. Also, as European standards through the Committee for European Normalization (CEN) TC251 Health Informatics committee. The end result is *a single set of internationally harmonized standards that have been developed and approved by all ISO and CEN countries*.
- These ISO/IEEE/CEN standards have been developed in *close coordination with other national and international standards development organizations*, including **HL7**, **DICOM**, **NCCLS**, and the **ANSI** Health Informatics Standards Board (HISB) and Medical Devices Standards Board (MDSB).
- A liaison between the IEEE 1073 standards group and the **FDA** Center for Devices and Radiological Health (CDRH) will help ensure that patient safety and efficacy concerns are fully addressed in the standards. By certifying conformance to a registered implementation profile (i.e., the device has successfully passed protocol conformance testing suites), it is hoped that the approval time for new device submissions to the FDA/CDRH can be reduced.
- The standards have been included in the National Committee on Vital and Health Statistics' (**NCVHS**) recommendations to the U.S. Department of Health and Human Services (**HHS**) related to patient medical record information (PMRI) message formats supporting Health Insurance Portability and Accountability Act (**HIPAA**) compliant implementations.
- Health care providers will have a wider array of medical device and information system options, reducing their dependence on sole-source vendors.
- Health care data collected from medical devices will be more easily archived and exchanged both within a health care enterprise, and between organizations that need to share information, nationally and internationally.
- Patient safety can be increased and health care delivery costs reduced.
- Next generation health care delivery systems can be developed and deployed with greater speed and lower cost.

For more information, see www.ieee1073.org.

¹ Technically, they provide all 7 layers of an ISO OSI 7-Layer communications model.