

IEEE Standard for Medical Device Communications—Overview and Framework

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Abstract: An overall definition of the IEEE 1073 family of standards is provided, describing the interconnection and interoperation of medical devices with computerized healthcare information systems in a manner suitable for the clinical environment.

Keywords: acute care, bedside environment, computerized healthcare information systems, medical devices, medical device system (MDS), patient care information system, patient data management system, virtual medical device (VMD).

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Introduction

(This introduction is not part of IEEE Std 1073-1996, IEEE Standard for Medical Device Communications—Overview and Framework.)

This standard for medical device communications defines a family of standards for providing interconnection and interoperability of medical devices and computerized healthcare information systems. Medical devices include a broad range of clinical monitoring, diagnostic, and therapeutic equipment. Computerized healthcare information systems similarly include a broad range of clinical data management systems, patient care systems, and hospital information systems.

This family of standards is firmly based on international standards for open systems communications and on the base layer standards and standardized profiles for the actual protocols and services specified.

This document is the top-level document in the family of documents comprising the IEEE 1073 family of standards. It is intended to provide the reader with an overview of the concept of medical device communications applied in this family of standards, as well as to provide a roadmap to the other documents in the family.

While complete references are provided to international documents where appropriate, the reader will greatly benefit from a familiarity with the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) documents for computer communication protocols, and particularly their basic reference model for Open Systems Interconnection (OSI) and related service and protocol definitions.

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IEEE Standard for Medical Device Communications—Overview and Framework

1. Overview

1.1 Scope

The scope of this family of standards is to provide for open systems communications in healthcare applications, primarily between bedside medical devices and patient care information systems, optimized for the acute care setting. The scope of this document is to provide the overall definition of the family of standards. It does so by defining a conceptual model, an information model, and a communications model for medical device communications and by specifying constraints for conformance to the set of standards.

1.2 Purpose

The purpose of the family of standards is to allow hospitals and other healthcare providers to allow medical instrumentation to interface with computerized healthcare information systems in a manner that is compatible with the acute care environment. The purpose of this document is to define the overall architecture for communications between medical devices and host computers and to provide a roadmap to the overall family of standards.

This document defines certain logical and functional entities, and as such no particular implementation is implied by this standard.

1.3 Key requirements

This standard is intended to enable medical devices to interconnect and interoperate with computerized healthcare information systems in a manner suitable for the clinical environment. The communications network described by this standard is distinguished from other types of conventional local area networks (LANs) in that it is optimized for the acute patient care setting. This context imposes several key requirements in the areas of reliability, network configuration, support for frequently changing host computer topologies, patient safety, and interface to healthcare personnel.

The key requirements are that this standard shall

- a) Meet applicable requirements for patient and user safety of medical devices.
- b) Accommodate frequent network reconfiguration.
- c) Provide an extremely simple user interface, the only required user action being to connect the medical device to the network.
- d) Unambiguously associate a medical device with a specific patient or bed.
- e) Support a wide range of host computer topologies, allowing implementations ranging from those limited to a single bedside to those that span multiple beds and care units, with various gradations between these extremes.
- f) Minimize implementation complexity for high-volume medical devices.

The survey data used to compile this list of requirements is provided in annex C of this standard.

Note that this standard defines certain optional services that may be used for device control operations. The choice to use or not to use these services is outside the scope of this standard.

1.4 Application and support

The scope of this standard does not preclude the use of the standard for domains that are outside of its scope. It is not the intent to define the requirements for, nor to optimize the standard for, those domains outside of its scope. It is intended to have wide application within the healthcare industry for the area of medical device communications.

The following paragraphs in this clause are intended to show potential applications and devices, but are not intended to be exhaustive, nor do they constitute a set of required items.

This standard is designed for use in, but not limited to, the following illustrative examples:

- a) Automation of the recording and entry of information from electronic medical devices
- b) Providing clinical personnel access to device status changes (e.g., alarms)
- c) Automation of adjustments of device settings derived from computed parameters

Medical devices vary greatly in the nature of the data they report. Devices of current clinical engineering technology broadly range from simple devices to intelligent devices. Simple devices generally only know about a single or small set of simple sensor readings. In particular, they know very little of the context of the data (e.g., units of measure, site, or method of measurement, etc.). Intelligent devices know a relatively large amount of information about the data and can provide much of the context of the data on demand. In addition to providing a standard for reliable transport of messages, this standard also provides for consistent syntax and semantics of those messages.

Examples of devices that might be interfaced via this standard include, but are not limited to,

- a) Physiologic parameter measurement and monitoring devices
- b) Ventilators and other respiratory therapy equipment
- c) Fluid infusion pumps and controllers
- d) Fluid drainage measurement and monitoring devices
- e) Bedside data entry devices