SLOVENSKI STANDARD
SIST ENV 13735:2003

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Zdravstvena informatika ï Medobratovalnost medicinskih naprav, priključ enih na pacienta

Health informatics - Interoperability of patient connected medical devices

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ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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Health informatics - Interoperability of patient connected medical devices

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Medical technology has developed in the context of rapid advances in the science of information technology and has benefited greatly by incorporating these advances into many medical devices. This has been done in a relatively unstructured manner with many devices being developed in isolation and in a way that precludes communication both between themselves and with hospital computer and data management systems. Those devices that can communicate generally use a proprietary communication protocol, which precludes connection to devices from different manufacturers.

The potential advantages of such communication are becoming more and more obvious. Consequently, there is a pressing need for technical standardisation and the development of services and protocols to enable such communication to exist in an easy and open way, with subsequent clinical, administrative and research benefits.

The first steps toward the development of such a standard were initiated by IEEE group p1073 in 1984 developing what has become know as the Medical Information Bus (MIB). The development of that set of standards has followed the ISO/OSI layers as demonstrated in the following figure:

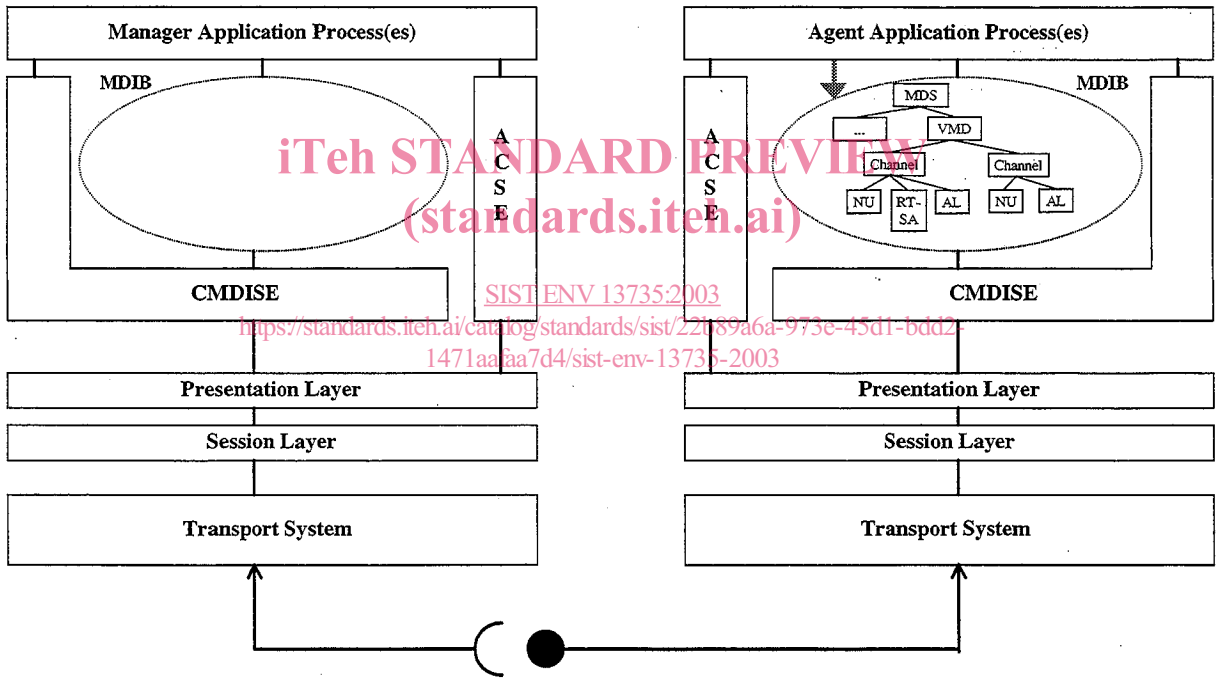

Figure 1 — . Example of agent manager communication system following ISO/OSI principals.

An essential element was the development of a standard for Vital Signs Information Representation, which covered the objects and attributes collectively known as the MDIB (area shaded in fig 1). This work has now been done (ENV 13734). The next stage, which is the focus of this project, is the development of necessary services and protocols, based on ISO/OSI standards, which enable true interoperability between medical devices. These cover the areas in the figure marked as ACSE, CMDISE, presentation layer and session layer. Interoperability of medical devices raises many technical, safety, and legal issues, which are worthy of consideration. The ongoing work of the IEEE standards group IEEE 1073 has been taken into consideration and reference is made particularly to their proposed standard 1073.2.0 Medical Device Application Profile (MDAP).

The primary user of this standard is a software engineer who is developing interface software for medical devices covered in the scope. This is one of a number of standards that the engineer should be familiar with, including the following:

ISO open systems interconnection (OSI) layered architecture.
IEEE 1073.1 MIB framework and overview.
CEN ENV 13734 "Vital Signs Information Representation"

1 Scope

This European standard applies to patient connected medical devices that can communicate patient related physiological data between devices and between a device and a computer system. Examples of applicable devices are given in annex E.

This standard specifies a communication controller model that should be used by applicable devices.

This standard states applicable references or specifies protocols including the ACSE, ROSE, CMDISE, presentation and session layer protocols that shall be used by applicable devices.

This standard defines application profiles that shall be used by applicable devices, and that shall be quoted by manufacturers when claiming conformance to this standard. Appropriate conformance statement templates are provided.

2 Normative reference(s)

The following normative documents contain provisions that, through reference in this text, constitute provisions of this CEN Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this CEN Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For an undated reference, the latest edition of the normative document referred to will apply.

IEEE 1073.2.0: Standard for Medical Device Communications – Medical Device Application Profile
IEEE 1073.3.1: 1996 Standard for Medical Device Communications - Transport Profile - Connection Mode
IEEE 1073.4.1: 1996 Standard for Medical Device Communications - Physical Layer Interface - Cable-connected
ENV 13734: 1999 Vital Signs Information Representation (VITAL)
ISO 7498-1: 1994 Information Technology - Open Systems Interconnection - Basic Reference Model
ISO 8649: Information technology - Open Systems Interconnection - Service definition for the Association Control Service Element
ISO 8824: 1990 Information technology - Open Systems Interconnection - Specification of Abstract Syntax Notation One (ASN.1).
ISO 8825 Information technology - Open Systems Interconnection - Specification of encoding rules for Abstract Syntax Notation One (ASN.1).
ISO 9596 Information technology - Open Systems Interconnection – Common Management Information Protocol Specification

3 Term(s) and definition(s)

3.1
Agent:
A Medical Device which provides data in a manager/agent communicating system.

3.2
Alarm:
A Signal which indicates abnormal events occurring to the patient or the device system.

3.3
Alert:
Synonym for the combination of patient-related physiological alarms, technical alarms and equipment user advisory signals.

3.4
Alert Monitor:
Object representing the output of a device or system alarm processor and as such the overall device or system alarm condition.

3.5
Alert Status:
Object representing the output of an alarm process that considers all alarm conditions in a scope that spans one or more objects.

3.6
Archival:
Relating to the storage of data over a prolonged period.

3.7
Association Control Service Element
Method used to establish logical connections between medical device systems.

3.8
Channel:
Umbrella object in the object model that groups together physiological measurement data and data derived from these data.

3.9
Class:
Description of one or more objects with a uniform set of attributes and services including a description of how to create new objects in the class.

3.10
Common Medical Device Information Service Element
With associated protocol provides services that allow access to the object instances in the Medical Data Information Base.

3.11
Communication Controller:
Part of a Medical Device System responsible for communications.

3.12
Communication Party:
Actor of the problem domain participating in the communication therein.

3.13
Communication Role:
Role of a party in a communication situation defining the party's behaviour in the communication. Associated with a communication role is a set of services which the party provides to other parties.

3.14
Data Format:
Arrangement of data in a file or stream.

3.15
Data Logger:
A medical device which is functioning in its capacity as a data storage and archival system.

3.16
Data Agent:
As a medical device a patient data acquisition system which provides the acquired data for other devices.

3.17
Data Structure:
Manner in which application entities construct the data set information resulting from the use of an information object.

3.18
Dictionary:
Description of the contents of the Medical Data Information Base containing vital signs information, device information, demographics, and other elements of the MDIB.

3.19
Discrete Parameter:
Vital signs measurement that can be expressed as a single numeric or textual value.

3.20
Domain Information Model:
The model describing common concepts and relationships for a problem domain.

3.21
Event:
A noteworthy occurrence that has a location in time and space.

3.22
Event Report:
Service (provided by the CMDISE) to report data relating to a managed object instance.

3.23
Framework:
A structure of processes and specifications designed to support the accomplishment of a specific task.

3.24
Graphic Parameter:
Vital signs measurement that requires a number of regularly sampled data points in order to be expressed properly.

3.25
Host system:
Term used as an abstraction of a medical system to which measurement devices are attached.

3.26
Information Objects:
Provide an abstract data model applicable to the communication of vital signs information and related patient data. The attributes of an information object definition describe its properties. Each information object definition does not represent a specific instance of real-world data, but rather a class of data which share the same properties.

3.27
Instance:
For example: object instance, application instance, information service element instance, VMD instance, class instance, operating instance

3.28
Intensive Care Unit:
Unit within a hospital in which critically ill patients are managed using multiple modes of monitoring and vital system supports.

3.29
Interchange Format:
The representation of the data elements and the structure of the message containing those data elements while in transfer between systems. The interchange format consists of a data set of construction elements and a syntax. The representation is technology specific.

3.30
Interoperability:
Idealised scheme whereby medical devices of differing types, models or manufacturers, are capable of working with each other, whether connected to each other directly or through a communication system. The communication system tracks location, connection, disconnection, replacement and re-siting of all devices.

3.31
Latency:
In a communications scenario latency is the time delay between sending a signal from one device and receiving it by another device.

3.32
Lower Layers:
Layers 1 to 4 of the ISO/OSI reference model. These layers cover mechanical, electrical and general communication protocol specifications.

3.33
Manager:
Device which receives data in a manager/agent communicating system.

3.34
Manager Agent model:
Communication model whereby one device (agent) provides data and another device (manager) receives data.

3.35
Medical Data Information Base:
The concept of an object oriented database storing (at least) vital signs information.

3.36
Medical Device System:
Abstraction for system comprising one or more medical devices.

3.37
Medical Devices:
Devices, apparatus, or systems used to prevent, measure, diagnose, or treat diseases in humans, and which do not normally enter metabolic pathways. For the purposes of this standard the scope of medical devices is further limited to those patient connected medical devices which provide support for electronic communications.

3.38
Monitor:
Patient data acquisition device designed to provide warning of possible patient deterioration.

3.39
Object Attributes:
Data, which, together with methods, define an object.

3.40
Object Class:
A descriptor used in association with a group of objects with similar properties (attributes), common behaviour (operations), common relationships to other objects, and common semantics.

3.41
Object Diagram:
Diagram showing connections between objects in a system.

3.42
Object Oriented Analysis:
Method of analysis described by Coad and Yourdon but the term Object-Oriented is used widely to describe similar techniques.

3.43
Object:
A concept, an abstraction or a thing with crisp boundaries and a meaning for the problem at hand.

3.44
Open System:
Set of protocols allowing computers of different origins to be linked together.

3.45
Operation:
A function or transformation that may be applied to or by objects in a class. (Sometimes also called service.)

3.46
Problem Domain:
The field of health care under consideration in a modelling process.

3.47
Protocol:
A standard set of rules describing the transfer of data between devices. It specifies the format of the data, and the signals to start, control and end the transfer.

3.48
Scanner:
Observer and "summariser" of object attribute values.

3.49
Scenario
Formal description of a class of business activities including the semantics of business agreements, conventions, and information content.

3.50
Service:
A specific behaviour that a communication party in a specific role is responsible for exhibiting.

3.51
Syntax:
The syntax of an Interchange Format (IF) describes the rules for combining the construction elements of the Interchange Format.

3.52
System:
Demarcated part of the perceivable universe, existing in time and space, that may be regarded as a set of elements and relationships between these elements.

3.53
Timestamp:
An attribute or field in data, which denotes the time of data generation.

3.54
Top Object:
Ultimate base class for all other objects belonging to one model.

3.55
Upper Layers:
Layers 5 to 7 of the ISO/OSI reference model. These layers cover application, presentation, and session specifications and functionalities.

3.56
Virtual Medical Device:
An abstract representation of a medical related subsystem of a Medical Device System.

3.57
Virtual Medical Object
An abstract representation of an object in the medical subject of the Domain Information Model.

3.58
Vital Signs:
Clinical information relating to one or more patients. It can be measured by or derived from apparatus connected to the patient, or it is otherwise gathered from the patient.

3.59
Waveform:
Here, used as graphic data, waveform data, varying data. Vital signs data, which is usually presented to the clinician in a graphical form.

4 Symbols (and abbreviated terms)

ACSE	Association Control Service Element
APDU	Application Protocol Data Unit
ASN.1	Abstract Syntax Notation One
BCC	Bedside Communication Controller
BER	Basic Encoding Rules
CC	Communication Controller
CEN	European Committee for Standardisation
CMDIP	Common Medical Device Information Protocol
CMDISE	Common Medical Device Information Service Element
DCC	Device Communication Controller
DIM	Domain Information Model
DIS	Department Information System
FSM	Finite State Machine
ID	Identification
IEEE	Institute of Electrical and Electronic Engineers
IF	Interchange Format
ISO	International Standards Organisation

LAN	Local Area Network
MDAP	Medical Device Application Profile (IEEE 1073.2.0 standard)
MDIB	Medical Data Information Base
MDS	Medical Device System
MIB	Management Information Base
MTU	Maximum Transmit Unit
OID	Object Identifier
OSI	Open Systems Interconnection
PDU	Protocol Data Unit
ROSE	Remote Operation Service Element
SNMP	Simple Network Management Protocol
SNTP	Simple Network Time Protocol
UML	Unified Modelling Language
VITAL	Vital Signs Information Representation standard ENV 13734
VMD	Virtual Medical Device
VMO	Virtual Medical Object
VSIR	Alternative abbreviation for VITAL defined above

5 Requirements

A Baseline Application profile and a Polling mode profile are defined in clause 9 In addition a set of optional packages may be required in order to provide for additional funtionality. Examples of the optional packages are outlined in informative annex A. Full definitions of all the optional packages are not the purpose of this standard and may be expected to appear in future documents.

Any medical device within the scope of this standard and claiming conformance to this draft standard shall do the following :

1. Shall conform to either a polling mode profile or a baseline profile and including any optional packages. Further conformance information is given in clause 9.

2. Shall provide a conformance statement in the format given which states what optional packages and what profile is used by the medical device.

3. Shall provide MDIB codes conforming to ENV 13734 'Vital Signs Information Representation'.

4. Should make use of the object models contained in this standard and ENV 13734 'Vital Signs Information Representation'.

5. Shall make references to object identifiers using codes as defined in ENV 13734 'Vital Signs Information Representation'.

6. Should use standards for layers 1-4 of the OSI Reference Model which are recognised as applicable to patient connected medical device communications.