SLOVENSKI STANDARD
SIST ENV 13734:2003

01-oktober-2003

Zdravstvena informatika – Predstavitev informacij o življenjskih znakih

Health informatics - Vital signs information representation

Informatik im Gesundheitswesen - Informationsdarstellung klinischer vitalparameter

Informatique de santé - Signaux physiologiques, représentation de l'information

Ta slovenski standard je istoveten z: **ENV 13734:2000**

ICS:

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

SIST ENV 13734:2003 **en**

EUROPEAN PRESTANDARD
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ICS 35.240.80

English version

Health informatics - Vital signs information representation

Informatique de santé - Signaux physiologiques, représentation de l'information

Informatik im Gesundheitswesen - Informationsdarstellung klinischer vitalparameter

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

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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

Rationale for this standard on Vital Signs Information Representation

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 measurement and other 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.

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

An essential element is the development of a standard for Vital Signs Representation, which in itself is a pre-requisite for the development of true interoperability.

Interoperability of medical devices raises many technical, safety, and legal issues which are worthy of consideration.

The relevant aspect of this document is the definition of a common device independent representation of Vital Signs Information and the definition of a common model for access of this information. Also the demands resulting from real-time communication have to be considered.

Development of this standard was based upon:

- The ISO Open Systems Interconnection Basic Reference Model.
- Identification and definition of information objects and their relationships based upon a set of scenarios with application of the object-oriented analysis and design methodology. Within CEN/TC251, during the production of this standard, the approach proposed by Coad and Yourdon has been followed.

Furthermore, the discussion and development work was guided by the CEN Technical Report CR1350: 1993 "Investigation of Syntaxes for Existing Interchange Formats to be used in Healthcare" and with consideration of the recently finished documents CEN prENV 12264 "Categorical Structure of Systems of Concepts - Model for Representation of Semantics (MOSE)" and CEN/TC 251/N95-295 Draft First Working Document "Categorical Structure of Systems of Concepts - Medical Devices". Respectively work and documents of the other TC 251 working groups have been considered and referenced.

Work on Standardization of Interoperability for Medical Devices has been carried on by various groups for more than ten years. The development of this standard would not have been possible without previous work done particularly by the IEEE Committee P 1073 and a number of national organizations in the field of Biomedical Engineering and Medical Informatics. Also, significant input has been obtained from other working groups of CEN/TC 251, particularly Working Group 2 dealing with Health Care Terminology, Semantics and Knowledge Bases, Working Group 3 dealing with Health Care Communications and Messages and Working Group 4 dealing with Medical Imaging and Multimedia. Where appropriate, reference is made in the text to their contributions.

Content of this standard for Vital signs information representation

The major parts of this standard are:

- The Domain Information Model (DIM).

  It is based upon scenarios for "off-line" data acquisition and archival, e.g. in sleep laboratories, and upon scenarios for departmental information systems in intensive care units with "on-line" communication. This communication takes place between a variety of interconnected medical device systems which may not only acquire data but also perform more or less extended processing.

- The Service Model for these communicating systems and devices.

- The dictionary for information elements of the Medical Data Information Base (MDIB) to be managed and communicated within the system.

This document is structured as follows:

- scope and field of application are defined;
- normative references, definitions and abbreviations are given;
- communication parties and their roles are described;
- the Domain Information Model and the Service Model are specified (in chapters 7 and 8);
- the dictionary for the elements of the MDIB and the methodology for the construction of its nomenclature is described (in chapter 9);
- the Normative Annex A contains the currently defined dictionary;
- the scenarios on which the Domain Information Model is based are given in Informative Annex B;
- a step by step example for communicating systems is given in Informative Annex C;
- other references are provided in Informative Annex D.

In order to understand the essential parts of the standard it is recommended that the step by step example be studied initially.

Field of Application

Figure 0.1 depicts a system where device 1 and device 2 are interconnected by a communication system.

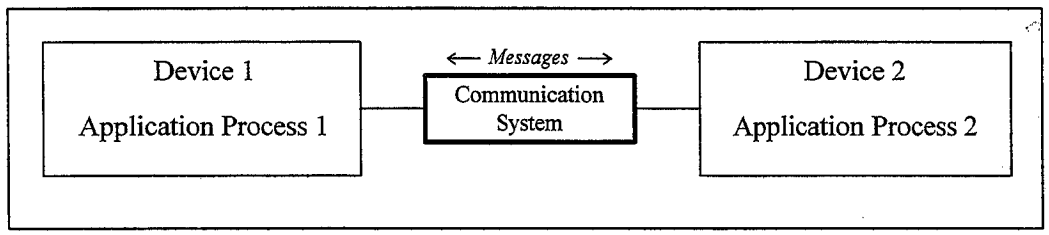

Figure 0.1: Two Communicating Devices

The "activities" (user functionalities) running on these devices, e.g. data acquisition on device 2, data display on device 1 are called application processes. Communication between these systems takes place by means of messages. The messages may contain the data, encoding information and control signals. The communication system block in Figure 0.1 represents hardware and software for interconnection of devices 1 and 2. The set of rules that define content and structure of the messages and their time relationships is called a "protocol" (ISO definition).