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Zdravstvena informatika – Izmenjava formatov podatkov v zvezi z življenjskimi znaki

Health informatics - File exchange format for vital signs

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

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CEN/TS 14271

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ICS

English version

Health informatics - File exchange format for vital signs

This Technical Specification (CEN/TS) was approved by CEN on 18 October 2003 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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Foreword

This document (CEN/TS 14271:2003) has been prepared by Technical Committee CEN/TC 251 " Health informatics", the secretariat of which is held by SIS.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

This document has been prepared by project team 40.

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

Introduction

From medical and clinical research new procedures and tests evolve continuously. Increasingly also dynamic tests are performed where often data from many hours of patient monitoring are acquired to be stored and to be processed. Also, healthcare is delivered by an increasing number of care providers.

To make cost effective use of the continuously growing medical information per patient, and in general communication and data integration, is of paramount importance. While today the public infrastructure for electronic transport of information is well developed, deficits in communication networks still exist within institutional healthcare providers (e.g. within hospitals) and between them.

There is first the open problem of the electronic health care patient record. Because of the different national and regional healthcare system requirements proposals for record specifications are still very divergent. Secondly, medical devices and device systems of different manufacturers differ in hardware and software, features as interconnectivity and interoperability are only slowly built in. Thirdly, the international uniform representation of demographic and medical information, and consequently the establishment of standards, is still incomplete.

This Technical Specification provides the specification for a universal File Exchange Format (FEF) within the domain of healthcare containing demographic data, administrative data and medical information (”Vital Signs Information”).

This Technical Specification is based upon the results of long expert discussion and practical experience in clinical work and international co-operation projects where the requirements for specification of a standard File Exchange Format for biosignals have emerged. Based upon all this previous work and based upon the previous prestandard for Vital Signs Information Representation (ENV 13734) this object oriented standardization proposal is presented. Its details are described in the following chapters.

Within Clause 1 – Scope – it is described which parts of the more generic Vital Signs Information Representation Standard, in particular, which subjects of the ENV 13734 Domain Information Model are covered by this document. Clause 2 lists the documents which need to be taken into account in implementing this Technical Specification. Clause 3 lists the definitions as they apply for the purpose of this document and Clause 4 lists the abbreviations used in this document. In Clause 5 the requirements are specified resulting from 3 fundamental data acquisition scenarios. Clause 6 presents the model of the File Exchange Format. The FEF model is presented using the Unified Modeling Language (UML) methodology. The global domain information model of the FEF file is given as well as submodels representing all the sections within the File Exchange Format. Clause 7 contains the detailed definitions and specifications for all sections of the File Exchange Format. Clause 8 specifies the required documents and the content of the documents for a conformance claim.

The normative Annex A contains the data dictionary which is an partial copy of the essential parts of the ENV 13734 Medical Data Information Base (MDIB) nomenclature, data dictionary and codes. As the codes for, e.g. physiological signals are not included here, the user needs to obtain the 13734 nomenclature or its successor documents (currently identified as IEEE ISO prEN 11073-10101) in order to implement this Technical Specification. Annex B gives the object definitions in ASN.1 and is normative in order to enable implementation of the File Exchange Format.

Users of other data formats may be overwhelmed by the large number of attributes and other details in this document. It should be noted that most attributes are optional. An implementer may use them only when helpful. In order to get a general overview of the format the reader is advised to take a look at Annex D for a simple example of the organization of normal biosignal data and events within the FEF.

1 Scope

This Technical Specification covers the off-line storage of biosignals, time-stamped measurements, events, enumerations and alerts as expressed in the CEN/TC251 prestandard Vital Signs Information Representation (ENV 13734). This Technical Specification defines a file data structure and not a message data structure. This Technical Specification does not support data compression. This Technical Specification includes a method to encapsulate or refer to one or many medical images, digital video and audio files but the intention is neither to define a new format for medical or other images, video nor audio. Figure 1 defines the scope of this Technical Specification with respect to ENV 13734.

In a small number of cases exact compatibility to ENV 13734 is not retained because of the chosen encoding. An example of this is the data type AbsoluteTime of ENV 13734 which is replaced with the ISO defined GeneralizedTime in this document (Section B.1.12).

Figure 2 defines the scope of this Technical Specification with respect to the archival subject in ENV 13734. This Technical Specification does not address the specification of the multipatient archive nor the patient archive. The ancillary object in this Technical Specification is the multimedia section.

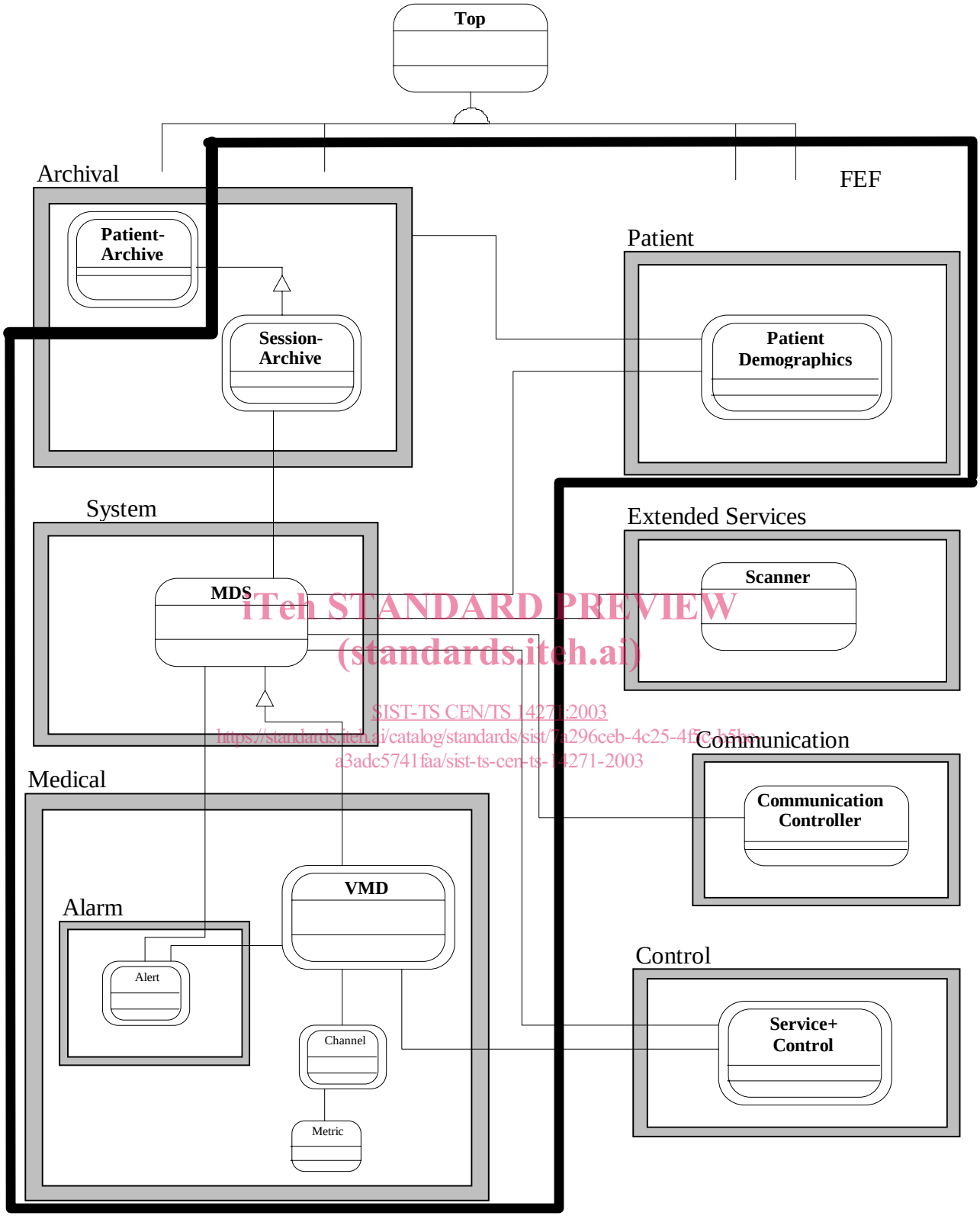

Figure 1- The area covered of ENV13734 by this Technical Specification is shown with the thick black line. (This figure is in Coad-Yourdon notation as the original ENV13734 is in this notation, as well.)

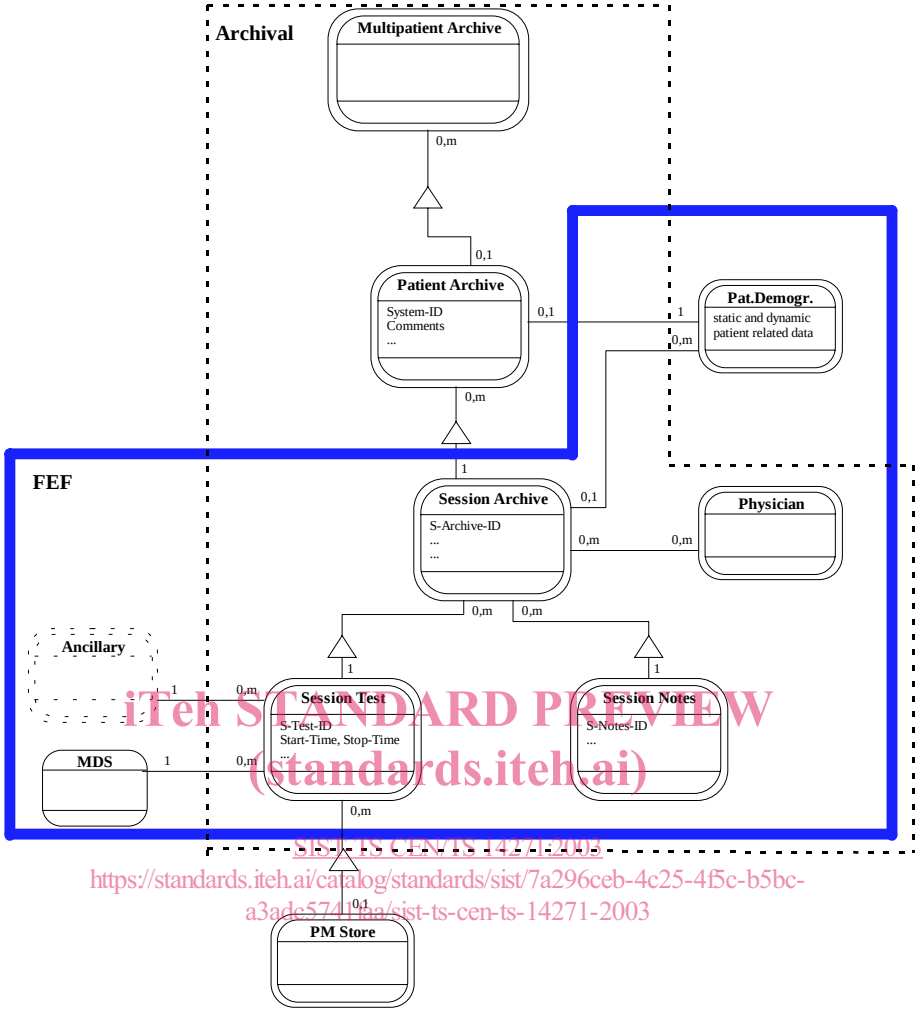

Figure 2 - The area covered of ENV 13734 by this Technical Specification with respect to the archival subject is shown with the thick line. The archival subject area in ENV 13734 is enclosed by the dashed line. (This figure is in Coad-Yourdon notation as the original ENV13734 is in this notation, as well.)

2 Normative references

ENV 1614:1994,	Medical Informatics - System of concepts for systematic names, classification and coding for properties, including quantities, in laboratory medicine
ENV 12264:1995,	Categorical Structures of Systems of Concepts - Model for Representation of Semantics (MOSE)
ENV 13734:1999,	Health Informatics - Vital Signs Information Representation (VITAL)
IETF- RFC 2046:1996,	Multipurpose Internet Mail Extensions (MIME) Part Two: Media Types.
IETF-RFC 2048:1996,	Multipurpose Internet Mail Extensions (MIME) Part Four: Registration Procedures.
ISO 41-0:1992,	Quantities and units - Part 0: General principles
ISO 5218:1977,	Information interchange - Representation of human sexes
ISO 8601:1988,	Data elements and interchange formats - Information interchange - Representation of dates and times
ISO/IEC 8824-1:1998,	Information Technology - Abstract Syntax Notation One (ASN.1): Specification of Basic Notation (ITU-T Recommendation X.680, 1997)
ISO/IEC 8825-1:1998,	Information Technology - ASN.1 Encoding Rules: Specification of Basic Encoding Rules (BER), Canonical Encoding Rules (CER) and Distinguished Encoding Rules (DER). (ITU-T Recommendation X.690, 1997)
ISO/IEC 10646-1:2000,	Information technology - Universal Multiple-Octet Coded Character Set (UCS). Part 1: Architecture and Basic Multilingual Plane

3 Definitions

For the purposes of this document, the following definitions apply:

Term	Definition
Alarm	Signal which indicates abnormal events occurring to the patient or the device system.
Alert	Synonym for the combination of patient-related physiological alarms, technical alarms and equipment user advisory signals.
Big Endian	Type of byte order in computer internal representation. Computer using this type numbers its bytes with byte 0 being the high-order (i.e., leftmost) byte.
Data Format	Arrangement of data in a file or stream.
Data Logger	A medical device which is functioning in its capacity as a data storage and archival system.
Data Structure	An aspect of data type expressing the nature of values that are composite, i.e. not atoms (an atom being a value that cannot be further decomposed). The non-atomic values have constituent parts (which need not themselves be atoms), and the data structure expresses how constituents may be combined to form a compound value or selected from a compound value.
Dictionary	Description of the contents of the Medical Data Information Base containing vital signs information, device information, demographics, and other elements of the MDIB.
Discrete Parameter	Vital signs measurement that it is possible to express as a single numeric or textual value.
Domain Information Model	The model describing common concepts and relationships for a problem domain.
Graphic Parameter	Vital signs measurement that requires a number of regularly sampled data points in order to be expressed properly.
Host system	Term used as an abstraction of a medical system to which measurement devices are attached.
Intensive Care Unit	Unit within a hospital in which critically ill patients are managed using multiple modes of monitoring and vital system support.
Interchange Format	The representation of the data elements and the structure of the file or stream 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.
Interoperability	Idealized 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.

Little Endian	Type of byte order in computer internal representation. Computer using this type numbers its bytes with byte 0 being the low-order (i.e., rightmost) byte.
Medical Data Information Base	The concept of an object oriented database storing (at least) vital signs information.
Medical Device System	Abstraction for system comprising one or more medical devices.
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 Technical Specification the scope of medical devices is further limited to those patient connected medical devices which provide support for electronic communications.
Object	A concept, an abstraction or a thing with crisp boundaries and a meaning for the problem at hand.
Object Attributes	Data which, together with methods, define an object.
Object Diagram	Diagram showing connections between objects in a system.
Open System	Set of protocols allowing computers of different origins to be linked together.
Scenario	Formal description of a class of business activities including the semantics of business agreements, conventions, and information content.
Streaming mode	Mode of data acquisition into a file in which other software modules than the data acquisition module accesses the data during its collection. In streaming mode it may be necessary to store enumerations, numeric measurements or alerts between blocks of waveform data.
Syntax	The syntax of an Interchange Format (IF) describes the rules for combining the construction elements of the Interchange Format.
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.
Tag	Identification information of a piece of data to follow, usually an unique number which distinguishes sections of data from other sections in the same level of hierarchy
Timestamp	An attribute or field in data which denotes the time of data generation.
Waveform	Here, used as graphic data, typically data values varying with respect to time. Vital signs data which is usually presented to the clinician in a graphical form. See also “graphic parameter”.
Virtual Medical Device	An abstract representation of a medical related subsystem of a Medical Device System.
Vital Sign	Clinical information relating to one or more patients. Measured by or derived from apparatus connected to the patient, or otherwise gathered from the patient.