

Health informatics — File exchange format for vital signs

ICS 11.020; 35.240.80

National foreword

This Draft for Development is the official English language version of CEN/TS 14271:2003.

This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature because of the limited duration of the European Technical Specification. It should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the European organization responsible for its conversion to a European Standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its 3-year life. Notification of the start of the review period will be made in an announcement in the appropriate issue of *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European Standard, to extend the life of the Technical Specification or to withdraw it. Comments should be sent in writing to the Secretary of BSI Technical Committee IST/35, Health informatics, at British Standards House, 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

Summary of pages

This document comprises a front cover, an inside front cover, the CEN/TS title page, pages 2 to 137 and a back cover.

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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.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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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.

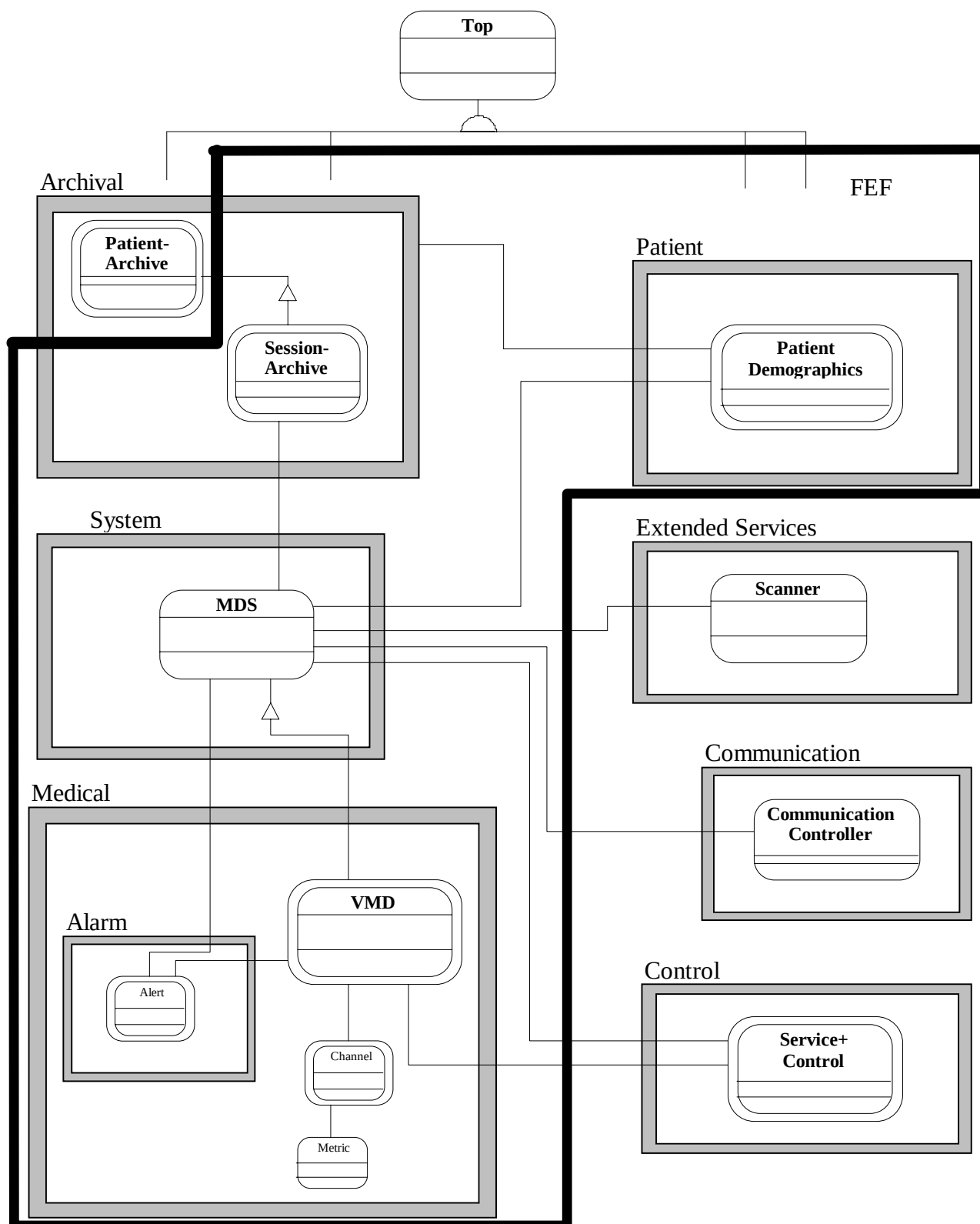


Figure 1- The area covered of ENV13734 by this Technical Specification is shown with the thick black line. (This figure is in Coad-Yourdon notation as the original ENV13734 is in this notation, as well.)

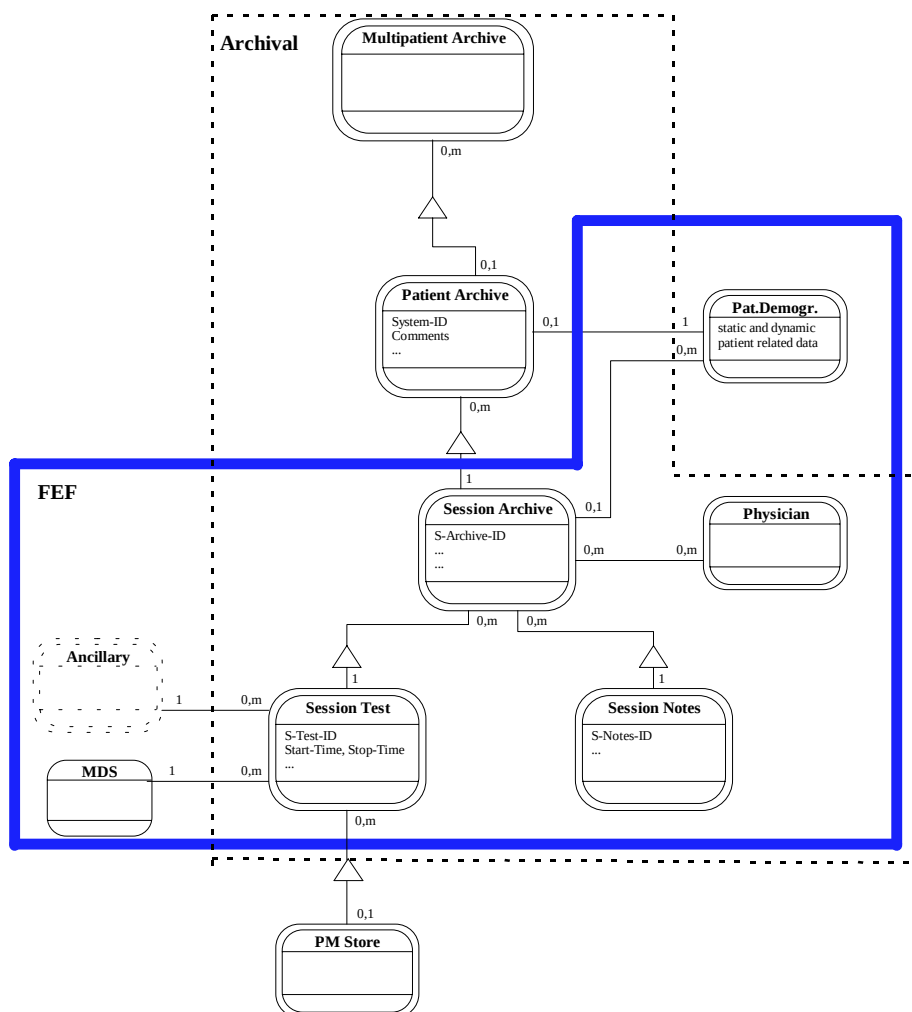


Figure 2 - The area covered of ENV 13734 by this Technical Specification with respect to the archival subject is shown with the thick line. The archival subject area in ENV 13734 is enclosed by the dashed line. (This figure is in Coad-Yourdon notation as the original ENV13734 is in this notation, as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

4 Symbols and abbreviations

For the purpose of this document, the following abbreviations apply.

A/D	Analogue-to-digital
AID	Attribute identification
ASCII	American Standard Code for Information Interchange
ASN.1	Abstract Syntax Notation One
CEN	European Committee for Standardization
DIM	Domain Information Model
DIS	Department Information System
ECG	Electrocardiogram
EEG	Electroencephalogram
FEF	File Exchange Format for Vital Signs
HIS	Hospital Information System
ICU	Intensive Care Unit
ID	Identification
IEEE	Institute of Electrical and Electronic Engineers
IETF	Internet Engineering Task Force
IF	Interchange Format
ISO	International Standards Organization
LAN	Local Area Network
MDIB	Medical Data Information Base
MDS	Medical Device System
OID	Object identification
OR	Operating Room
PT	Project Team
SA	Sample Array
TC	Technical Committee
WAN	Wide Area Network

WG	Working Group
VMD	Virtual Medical Device
VS	Vital Signs

5 Requirements

The file exchange format is applicable to computer systems used in medical applications independent of the specific hardware technology. The FEF specification covers all vital signs information described within the VITAL domain information model. The information represented in the VITAL document is serialised here in order to produce a file or a set of files which can be stored or exchanged after the completion of vital signs signal acquisition. In order to make the work with the archived signal data easy the file exchange format should allow fast access to all pieces of data but nevertheless the format should be efficient for storing the data on any media. To be manageable and implementable the standard should be short and simple enough still allowing the required flexibility.

The FEF has to be organised in sessions of vital signs data acquisition. Several session tests of vital signs data acquisition form a session archive. One or more session archives are available for each patient. Never should one session archive contain information for more than one patient. This results already in a specific restricted view on the VITAL domain information model.

Each session archive contains one or many session tests of vital signs data acquisition. Each session test consists of one or many session phases. One such session phase will represent an archive of continuous flow of data (which may be empty). If there is an interruption to the continuous flow of data, e.g. one test ended, a patient was disconnected from the monitoring and moved to a different ward, then the session phase ends and in case of further recording a new session phase has to be created. Changes in signal amplitudes, number of signals recorded, should be allowed in one session test but not in one session phase.

To specify changes of signal characteristics and number of signals, one session test of vital signs data acquisition may contain one or several phases of vital signs data acquisition. One phase always contains one and not more than one block of descriptive data which specify the vital signs acquired. One phase may contain many measured data blocks.

One session test contains one or many session phases. A session test combines the phases which belong together from a medical perspective. A session test may be the recording of a patient during the entire stay on an intensive care unit. It may be one continuous night recording with just one session phase or a set of many neurophysiological investigations which together form one test. For practical reasons (search in the file) only a limited number of session phases will be taken together in one session test and one physical data file.

6 Model of the File Exchange Format

6.1 Conceptual Background

FEF incorporates a major subset of the data elements of the domain information model of ENV 13734, Vital Signs Information Representation (VITAL). Figure 1 in Clause 1, taken from ENV 13734, shows which parts of the domain are addressed in the scope FEF. FEF constitutes a natural sequence of VITAL in the direction of the definition of a vital signs file exchange format.

The model of FEF is presented using the Unified Modelling Language (UML) methodology. Mainly the Use Cases and Class diagrams of this methodology are used in the modelling of FEF.

6.2 Use case model

Following a high abstraction overview, given on this subclause, some subclauses are presented where more detailed models of the FEF domain information model are presented. They contain successive lower levels of abstraction and provide a more profound conceptual view of FEF. It is the intention that this clause provides the sufficient insight on the format conceptual structure that enables the interpretation of the detailed definition given in the next clause.

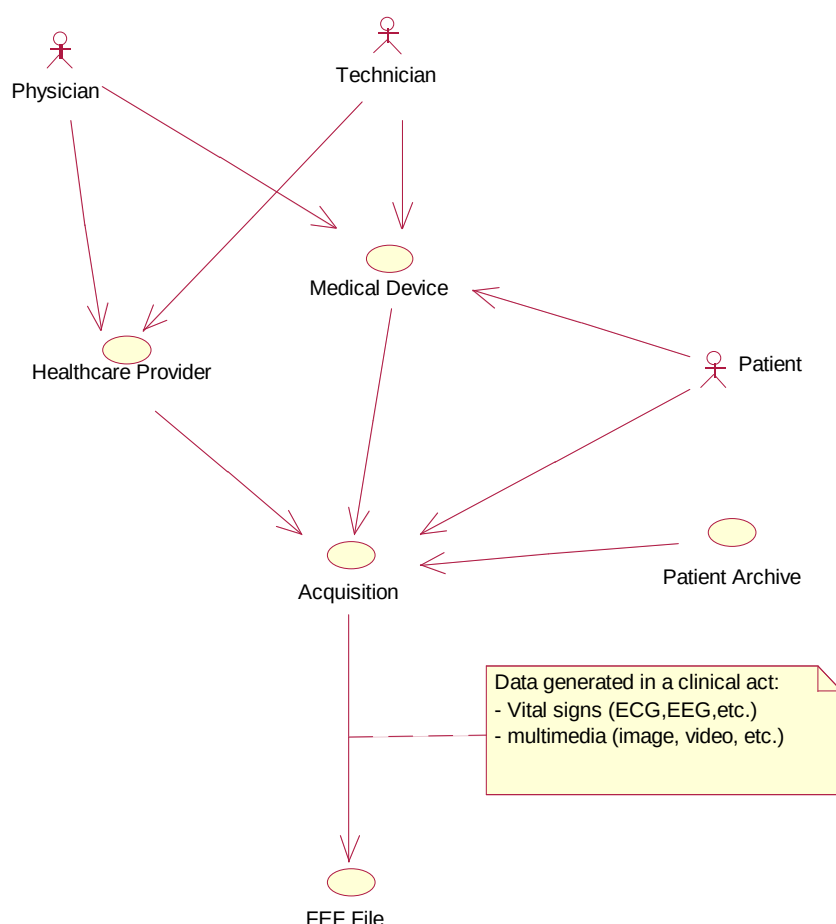


Figure 3 – High abstraction Use Case diagram showing actors and types of data contained in FEF

One of the basic assumptions behind FEF is its capacity to accommodate the diversity in nature of data present in the Vital Signs (VS) healthcare environment. Given this assumption and the previous work of VITAL it is concluded that FEF will be associated to several "types of data" and actors. Fig. 3 presents a Use

Case model that reflects the general overview of the application domain of FEF. The types of data and actors identified are:

- patient related data, from clinical data to administrative and demographic information
- healthcare actors, including healthcare provider and healthcare professionals
- healthcare resources, including medical device details such as manufacturer information
- the data itself, particularly vital signs information and, optionally, audio, images and video (multimedia). All possible events registered during the VS acquisition sessions, session notes taken during a data acquisition, etc. are also considered to be included in this data

6.3 Domain Information Model

6.3.1 General

The domain information model (DIM) of FEF expresses the file architecture and associated concepts. It is a compromise between a conceptual vision over the VS healthcare environment and practical issues related to a concrete file exchange format. The design of the FEF is intended to be flexible enough to adapt to different VS healthcare domain applications. One basic assumption that fulfils these requisites is the definition of the format in which data are stored to a file in different sections. The global DIM of FEF is presented in the class diagram of Fig. 4.

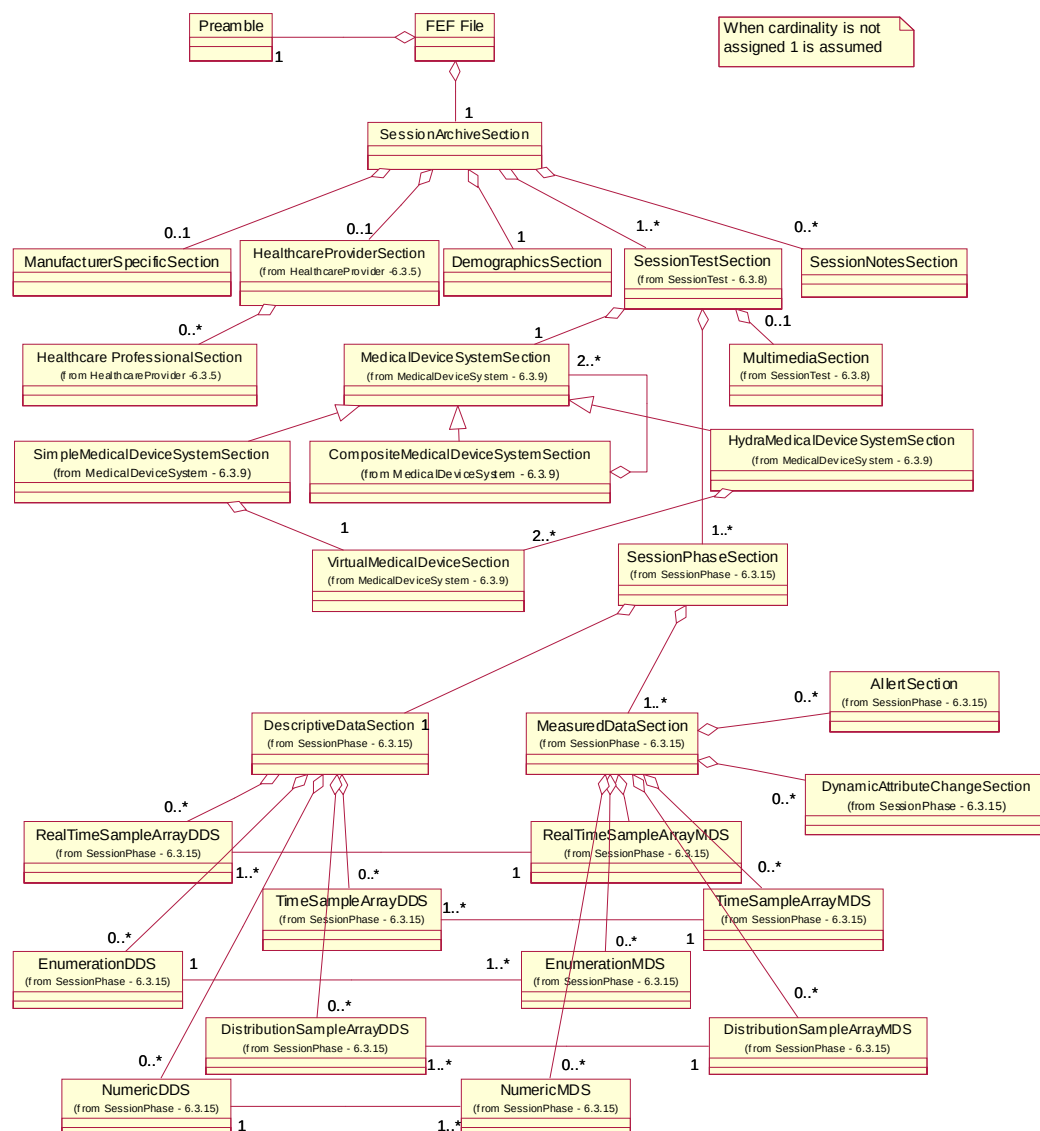


Fig 4 -Global Domain Information Model (DIM) of FEF file.

This model reflects the sections in which FEF is organised and their relationships. To simplify this description the DIM global model is described by several sub-models along this clause of the related sections of FEF.

The DIM of FEF is strongly based of the domain model of VITAL reproduced in this document in Fig. 1. The direct mapping between objects of VITAL and FEF is given in table 1.

Table 1: Direct mapping in FEF of objects defined in VITAL

VITAL	FEF
SessionArchive	SessionArchiveSection
PatientDemographics	DemographicsSection
Physician	HealthcareProfessionalSection
SessionTest	SessionTestSection

Table 1 (continued)

SessionNotes	SessionNotesSection
MedicalDeviceSystem	MedicalDeviceSystemSection
SimpleMedicalDeviceSystem	SimpleMedicalDeviceSystemSection
HydraMedicalDeviceSystem	HydraMedicalDeviceSystemSection
CompositeMedicalDeviceSystem	CompositeMedicalDeviceSystemSection
VMD	VMDSection

In this mapping procedure the names defined in VITAL have been maintained adding a qualifier word "Section". In the case of the "Physician" object its FEF counterpart has been named as "Healthcare professional" for generality purposes. A new hierarchical level – "Healthcare Provider Section" has been introduced to enable extensibility of this level and to be able to incorporate here other information such as technicians or hospital departments associated to the file life cycle. The VITAL domain model is expanded by adding new objects such as *Manufacturer Specific Section* - needed to store manufacturer specific information associated to the file – and *Multimedia Section* - added to enable the inclusion or linking of the data in FEF to other (multimedia) data such as medical images, video and audio.

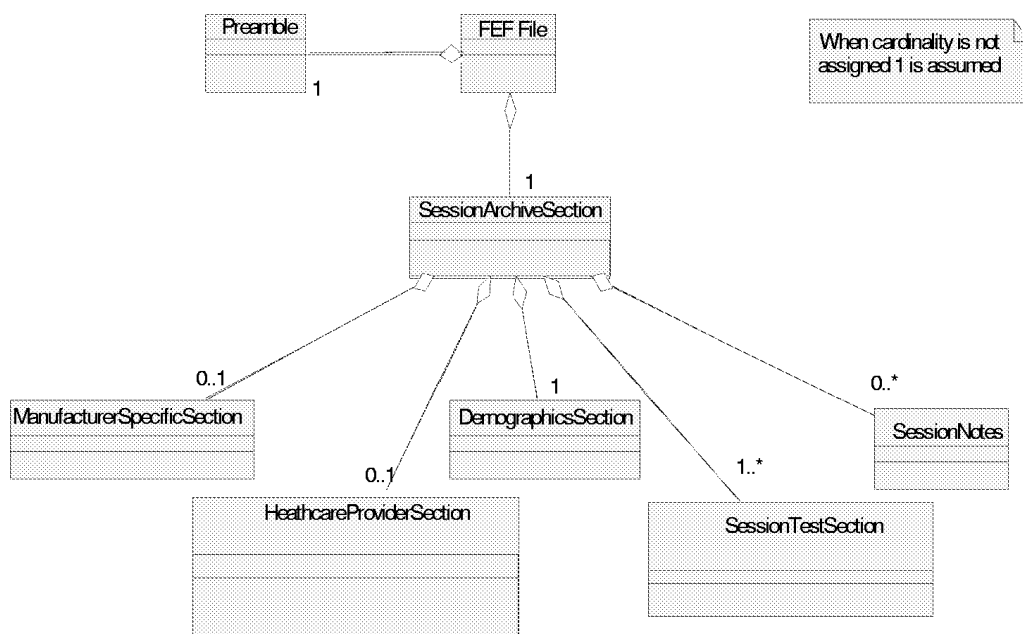


Figure 5 – High abstraction sub-model of the FEF DIM

The first sub-model is the high abstraction view of the DIM which shows the top of the hierarchic structure of FEF. In this sub-model presented in Fig. 5 FEF is composed of two main sections: *Preamble* and *Session Archive Section*. This section, in turn, is composed by other 5 sub-sections: *Manufacturer Specific*, *Healthcare Provider*, *Demographics*, *Session Test* and *Session Notes*. Detail of these parts of the model follows in the next subclauses.

6.3.2 Preamble

The *Preamble* is a short section containing an identification « finger print » which programs can use to verify that the file is of correct type and some global information concerning the file such as a code which defines whether little or big endian representation is used in multi-byte binary numbers.

6.3.3 Session Archive Section (SAS)

The Session Archive Section is the root type of the abstract syntax defined in this document. The Session Archive Section represents a patient visit or a continuous stay in the a hospital or hospital department.

Diagnostic treatments performed during this time period are represented by Session Test Sections contained in the Session Archive.

6.3.4 Manufacturer Specific Section (MSS)

The optional manufacturer specific section stores manufacturer specific information.

6.3.5 Healthcare Provider Section (HPvS)

The Healthcare Provider Section can store information associated with the institution and department(s) of that institution (unusually the location in which the file was written) that have any kind of action in the file life cycle. All healthcare professionals belong to the Healthcare Provider in this model.

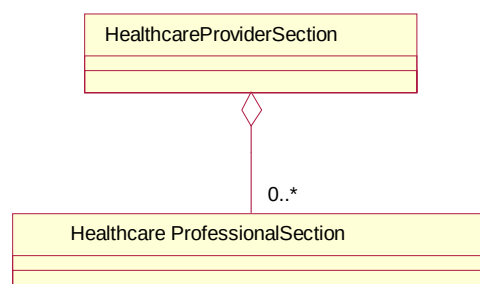


Figure 6 - Sub-model of the Healthcare Provider Section of FEF

6.3.6 Healthcare Professional Section (HPfS)

The healthcare professional sections store information about healthcare professionals (e.g. physicians, technician, nurse...) involved in acquiring the vital signs or otherwise related to the patient. Reference to healthcare professional is done using the handle and the role of the healthcare professional is established by the field which refers to this handle.

6.3.7 Patient Demographics Section (PDemS)

Patient Demographic Section stores patient related information such as name, date of birth, sex etc. which are likely to remain constant during the measurement. The information is mostly stored in text strings and viewed by humans rather than processed by computers.

6.3.8 Session Test Section (STS)

The Session Test Section represents a patient visit or a continuous stay in a hospital or hospital department. The Session Test Section contains vital signs information of a single patient that is recorded during a single examination or diagnostic treatment. The object contains vital signs metrics grouped into phases of constant acquisition parameters.

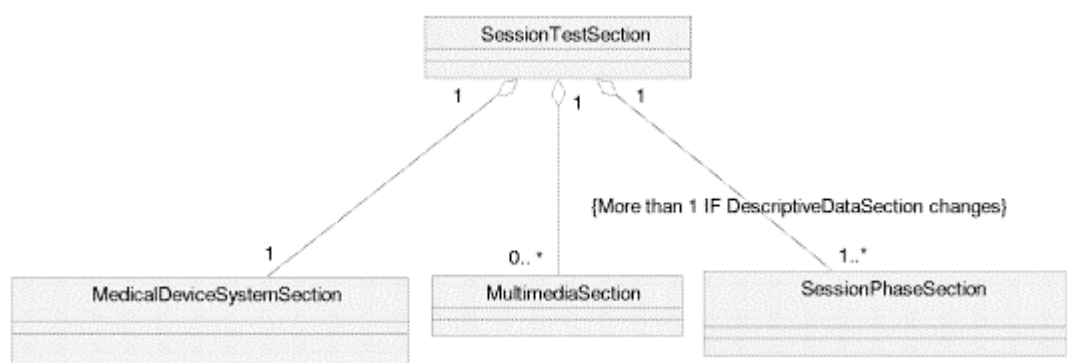


Figure 7 - Sub-model of the Session Test Section of FEF

6.3.9 Medical Device System Section (MDSS)

A MedicalDeviceSystemSection stores the composition of medical devices or subsystems which participate in the collection of vital signs information. A MedicalDeviceSystemSection can contain either a single VirtualMedicalDeviceSection section (Simple MDS case), or multiple VirtualMedicalDeviceSections (Hydra MDS case) or multiple MedicalDeviceSystemSections denoting subsystems (Composite Single Bed MDS case). There always exists one root MedicalDeviceSystemSection in a Session Test Section. Each Session Test Section shall contain at least one Medical Device Section.

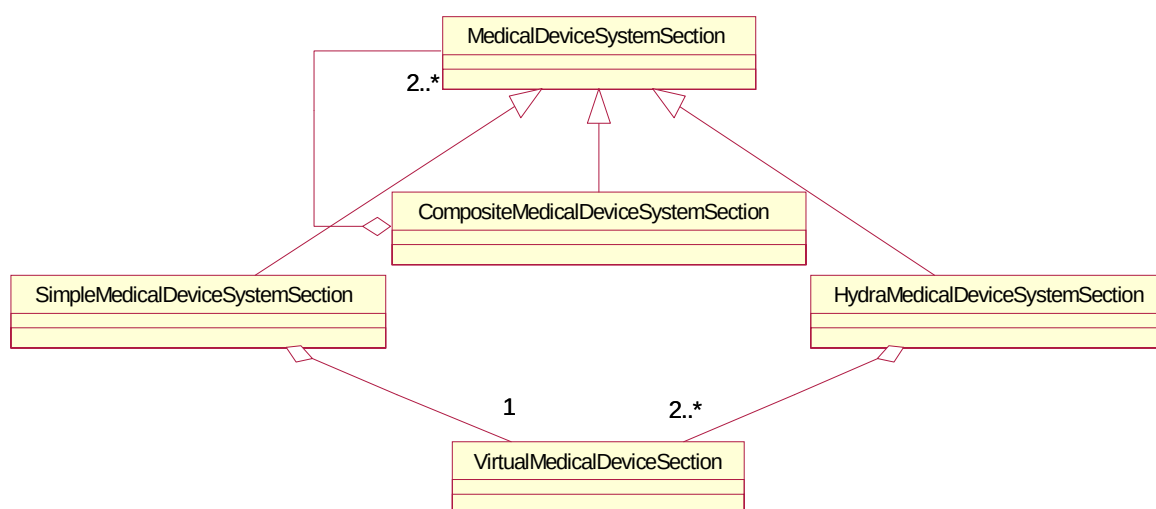


Figure 8 - Sub-model of the Medical Device System Section of FEF

6.3.10 Virtual Medical Device Section (VMDS)

The VirtualMedicalDeviceSection stores information for a single medical device of a medical device system. It represents a physical component of a medical device system or a function of a medical device system. If there are measurement values in the file, there must also have been a device which has measured them and therefore there must also be at least one Virtual Medical Device Section. If a real medical device consists of more than one functional component with serial numbers etc., these components shall be declared as different devices.

6.3.11 Channel Description Section (CDS)

The Channel Description Section (CDS) corresponds to the ENV13734 class Channel. The CGS can be used to group vital signs. Its use is optional.

6.3.12 Multimedia Section (MMS)

As there is a need to store also patient-related images, audio and video when vital signs are monitored, the file exchange format incorporates also a standardised method for storing these data. The data can be included in the file or referenced. This specification does not define image, audio or video storage formats but it recommends that one of the registered MIME formats¹⁾ be used. For unregistered media types an extension mechanism is defined in 7.3.12.

6.3.13 Session Phase Section (SPS)

Diagnostic procedures performed during the patient test duration are represented by SessionPhaseSections contained in the SessionTestSection. It contains the descriptive and measured data for a phase of a session test, during which the number of channels and all their parameters (gains, units etc.) do not change.

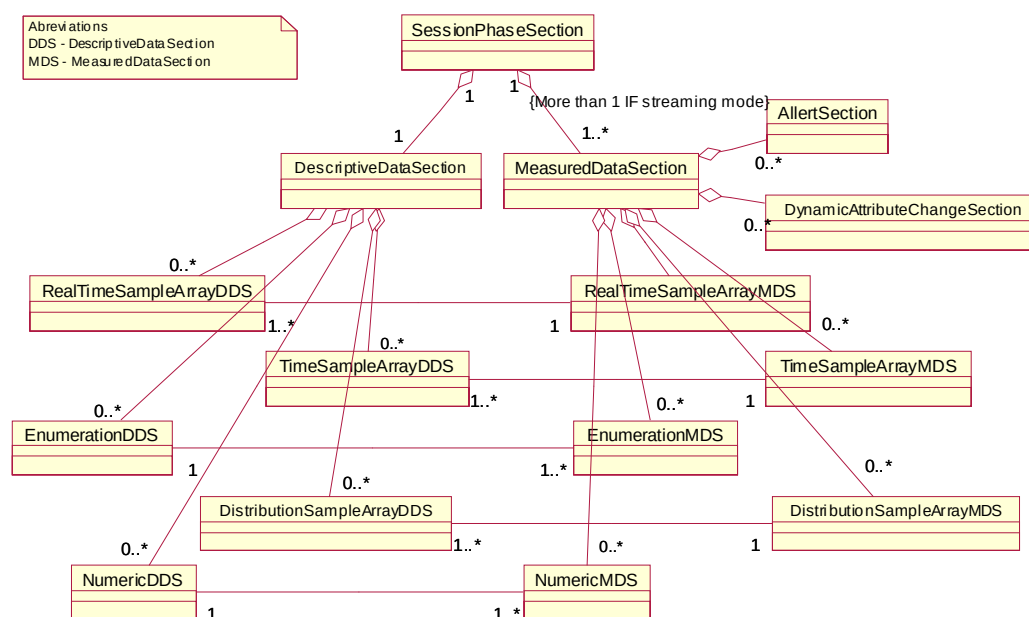


Figure 9 - Sub-model of Session Phase section of FEF

6.3.14 Descriptive Data Section (DescDS)

The DescriptiveDataSection (DDS) stores descriptions of all vital signs recorded. The static and dynamic attributes of the classes derived from ENV13734 Metric are stored in the DDS. Five possible DDS can be contained in this section: RealTimeSampleArray, TimeSampleArray, Enumeration, DistributionSampleArray and Numeric. These sections are detailed below.

6.3.15 Metric Descriptive Data Section (MDDS)

The MetricDescriptiveDataSection stores the static and dynamic attributes of the ENV13734 class Metric. As abstract classes are never instantiated, this sections are never stored themselves in the file but rather hold attributes shared by other sections.

1) The current list of registered types can be obtained from <ftp://ftp.isi.edu/in-notes/iana/assignments/media-types/>

6.3.16 Sample Array Descriptive Data Section (SADDS)

The SampleArrayDescriptiveDataSection stores the static and dynamic attributes of the ENV13734 class SampleArray. As abstract classes are never instantiated, this sections is never stored themselves in the file but rather hold attributes shared by other sections.

6.3.17 Real Time Sample Array Descriptive Data Section (RTSADDS)

The RealTimeSampleArrayDescriptiveDataSection stores the static and dynamic attributes of the ENV13734 class RealTimeSampleArray.

6.3.18 Time Sample Array Descriptive Data Section (TSADDS)

The TimeSampleArrayDescriptiveDataSection stores the static and dynamic attributes of the ENV13734 class TimeSampleArray.

6.3.19 Distribution Sample Array Descriptive Data Section (DSADDS)

The DistributionSampleArrayDescriptiveDataSection (DSADDS) stores the static and dynamic attributes of the ENV13734 class DistributionSampleArray.

6.3.20 Numeric Descriptive Data Section (NDDS)

The NumericDescriptiveDataSection stores the static and dynamic attributes of the ENV13734 class Numeric.

6.3.21 Enumeration Descriptive Data Section (EDDS)

The EnumerationDescriptiveDataSection stores the static and dynamic attributes of the ENV13734 class Enumeration.

6.3.22 Measured Data Section (MeasDS)

The MeasuredDataSection stores data measured of all vital signs recorded. The observed attributes of the classes derived from ENV13734 Metric are stored in the MeasuredDataSection. For the streaming mode profile only, the SessionPhaseSection may hold more than one MeasuredDataSection.

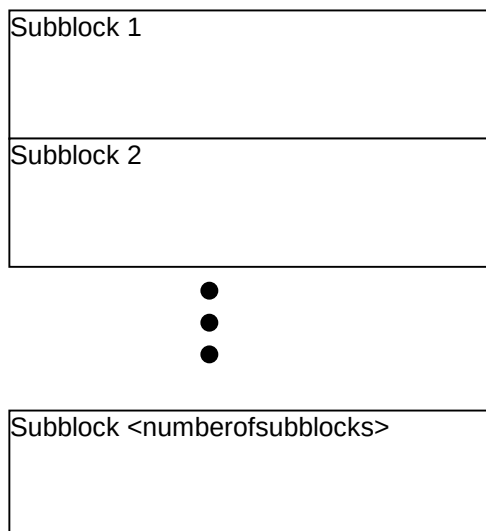
6.3.23 Sample Array Measured Data Section (SAMDS)

The SampleArrayMeasuredDataSection stores observed attributes of one or more objects of ENV13734 class SampleArray. The possibility to store the observed attributes of more than one objects in this section was introduced for efficiency and for easy translation from and to existing file formats. SampleArrayDescriptiveDataSection and SampleArrayMeasuredDataSection store signals equidistantly sampled. As abstract classes are never instantiated, this section is never stored itself in the file but rather hold attributes shared by other sections.

6.3.24 Sample Array Measured Data Block (SAMDB)

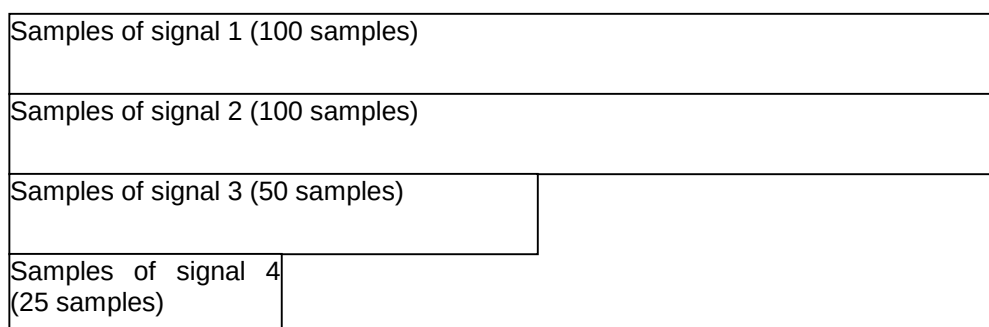
The actual scaled samples are stored in the Sample Array Measured Data Block as a Binary Large Object (BLOB). The encoding rules may put this BLOB in the same file, which is preferred, or in a separate file, to which a referral is given. For the case of all samples being 16 bit signed integers, this SAMDB matches the data block of the 'European Data Format' as being described earlier ²⁾.

2) Kemp, B., Värri, A., Rosa, A.C., Nielsen, K.D. and Gade, J. A simple format for exchange of digitised polygraphic recordings. *Electroenceph. clin. Neurophysiol.*, 1992; 82:391-3.



The SAMDB is divided into <numberofsubblocks> subblocks each of which have a size of <subblocksize> octets. Each subblock contains samples from all measured signals belonging to the session phase section in question. The number of samples of each signal is the same in all subblocks but all signals do not have to have the same number of samples in a subblock. This enables the use of different sampling frequencies to the signals.

The samples of each signal are stored consecutively within a subblock. The order of signals is indicated by the order of the handle references in the <metriclist> of each SAMDS. The number of signals in a subblock is the number of items in the <metriclist>. The number of samples/signal in a subblock is indicated by <arraysize> attribute in the <SaSpec> section of SADDs. It can also be calculated as <subblocklength> divided by <sampleperiod> of the signal. This number has to be an integer number and it has to match the <arraysize> attribute value. For distribution sample arrays the <arraysize> attribute is the only information indicating the number of samples of a signal in a subblock. Below is an example of a subblock of four signals with different sampling rates.



The following pseudocode shows how to determine the storage offset for the first sample of each metric in a subblock and the number of samples per subblock:

```
offset = 0;

for (metric IN metriclist) {
    metric.samplespersubblock = subblocklength/metric.sampleperiod;
    metric.offset = offset;
    offset = offset + metric.samplespersubblock * metric.storagesize/8;
}
```

The following pseudocode shows how to access sample N of a metric:

```
position = (N div metric.samplespersubblock) * subblocksize;  
  
position = position + metric.offset;  
  
position = position + (N div metric.samplespersubblock) * metric.storagesize/8;  
sample = subblock[position]
```

6.3.25 Real Time Sample Array Measured Data Section (RTSAMDS)

The RealTimeSampleArrayMeasuredDataSection stores observed attributes of one or more objects of ENV13734 class RealTimeSampleArray. The possibility to store the observed attributes of more than one object in this section was introduced for efficiency and for easy translation from and to existing file formats. RealTimeSampleArraySpecificationDataSection and RealTimeSampleArrayMeasuredDataSection store signals equidistantly sampled for the entire duration of the Session Phase, for example ECG.

6.3.26 Time Sample Array Measured Data Section (TSAMDS)

The TimeSampleArrayMeasuredDataSection stores observed attributes of one or more objects of ENV13734 class TimeSampleArray. The possibility to store the observed attributes of more than one objects in this section was introduced for efficiency and for easy translation from and to existing file formats. TimeSampleArraySpecificationDataSection and TimeSampleArrayMeasuredDataSection store signals equidistantly sampled for (usually small) time periods within a Session Phase, for example Evoked Potentials single sweeps or averages.

6.3.27 Distribution Sample Array Measured Data Section (DSAMDS)

The DistributionSampleArrayMeasuredDataSection stores observed attributes of one or more objects of ENV13734 class DistributionSampleArray. The possibility to store the observed attributes of more than one object in this section was introduced for efficiency and for easy translation from and to existing file formats. DistributionSampleArraySpecificationDataSection and DistributionSampleArrayMeasuredDataSection store signals equidistantly sampled over a dimension other than time, for example power spectra.

6.3.28 Numeric Measured Data Section (NMDS)

The NumericMeasuredDataSection stores observed attributes of the one object of ENV13734 class Numeric.

6.3.29 Enumeration Measured Data Section (EMDS)

The EnumerationMeasuredDataSection stores observed attributes of one object of ENV13734 class Enumeration.

6.3.30 Alert Section (AS)

The AlertSection stores the result of single alarm condition check. The alarm can either be a physiological alarm or a technical alarm condition relating to a Medical Device System, Virtual Medical Device or Metric. Whereas ENV 13734 provides additionally the Alert Status and Alert Monitor objects to query an integrated or summary view of alarm conditions, the FEF file will always record the Alert events themselves only.

6.3.31 Dynamic Attribute Change Section (DACS)

The DynamicAttributeChangeSection stores changes of selected dynamic attributes during a Session Phase. Most changes of dynamic attributes are disallowed in a Session Phase and new Session Phase Section shall be written if, for example, gains or filter settings are changed.

6.3.32 Session Notes (SNS)

The SessionNotesSection contains comments, findings and diagnoses which concern the whole Session Test or Session Archive in question.

7 Specification of FEF Sections

7.1 General

A file produced according to this specification consists of sections. Some sections are obligatory, some sections are alternative and some sections are optional. An overview of the section structure is presented in Figure 10

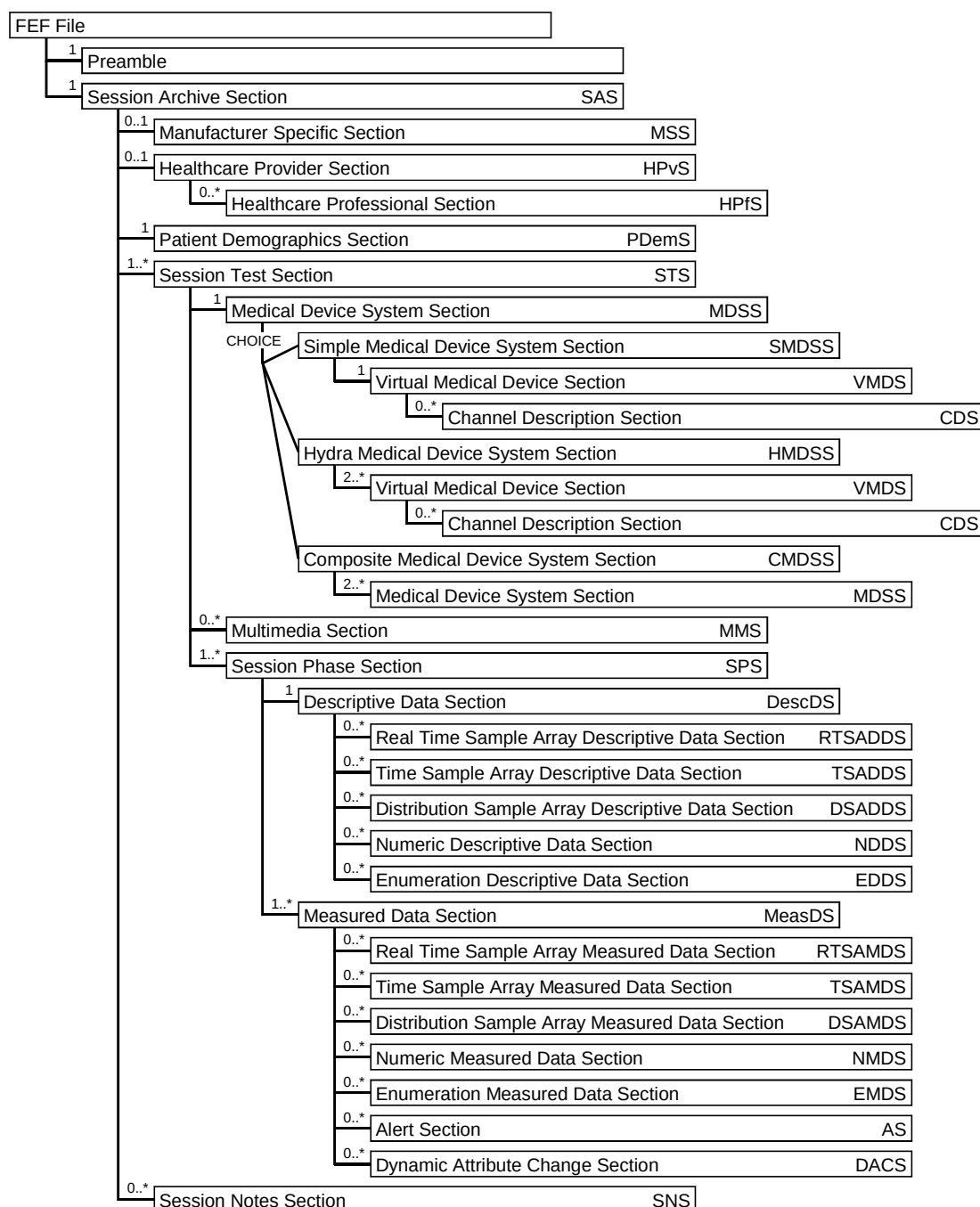


Figure 10 - The section structure of FEF. Notation: 0..1 in front of a box means that either zero or one such section or subsection can be present. 0..* means that zero or more such sections can be present. 1 means that only one such section can be present. CHOICE means that only one of the following elements can be present.

7.2 Encoding

The encoding of the data format is defined in the normative Annex B section of this document. Other encoding alternatives are possible in future if they are specified and accepted by recognized international standardisation bodies.

7.3 Definition of the file format

7.3.1 Data types

The following data types are used in the attributes of different sections. Their practical realisation depends on the applied encoding rules. Annex B specifies the encoding using ASN.1 Basic Encoding Rules.

Integer data types

Name	Type	Remark
INT-U64	INTEGER	Purpose is to store unsigned 64-bit integer
INT-I64	INTEGER	Purpose is to store signed 64-bit integer
INT-U32	INTEGER	Purpose is to store unsigned 32-bit integer
INT-I32	INTEGER	Purpose is to store signed 32-bit integer
INT-U16	INTEGER	Purpose is to store unsigned 16-bit integer
INT-I16	INTEGER	Purpose is to store signed 16-bit integer
INT-U8	INTEGER	Purpose is to store unsigned 8-bit integer
INT-I8	INTEGER	Purpose is to store signed 8-bit integer

Bit string data types

Name	Type	Remark
BITS-32	BIT-STRING	Purpose is to store 32-bit bit string
BITS-16	BIT-STRING	Purpose is to store 16-bit bit string
BITS-8	BIT-STRING	Purpose is to store 8-bit bit string

FEFString

Type FEFString is UTF8String.

FEFFloat

Type FEFFloat is REAL.

Fraction

Type Fraction is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Numerator	1	INT-32	1	
Denominator	1	INT-32	2	

AbsoluteRange

Type AbsoluteRange is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Lowervalue	1	FEFFloat	1	
Uppervalue	1	FEFFloat	2	

Handles and codes

Name	Type	Remark
Handle	INT-U16	The Handle type holds locally unique (within a file) values to identify sections of the file. Within a single file no two instances of the Handle type hold the same value.
HandleRef	INT-U16	HandleRefs link sections to other sections, e.g. linking a descriptive data section to a corresponding measured data section. HandleRefs link also measurements and events to devices, e.g. by linking an alert to a virtual medical device.
DeviceCode	INT-U16	DeviceCode defines the type of the device from the device code table of the data dictionary of Annex A.
UnitsOfMeasurementCode	INT-U16	UnitsOfMeasurementCode defines the applied unit of measurement from the units of measurement table in the data dictionary of Annex A.
MetricsCode	INT-U16	MetricsCode defines the measured metric from the metrics table in the data dictionary of Annex A. MetricsCode is used in such cases where ENV 13734 uses OID-Type and refers particularly to the Metric partition of Annex A.
BodySiteCode	INT-U16	BodySiteCode defines the body site of the measurement using the codes in the body site code table of Annex A.
AlertCode	INT-U16	AlertCode defines the type of the alert using the codes in the alert code table of Annex A.
ExtNomenclatureCode	INT-U16	ExtNomenclatureCode defines which external nomenclature is applied in coding a specific entity. The codes for different external nomenclatures can be found in the corresponding table in Annex A.
ParameterGroupCode	INT-U16	ParameterGroupCode refers to the classification of the measurement, e.g. cardiovascular. At this time only the private area of this code space can be used as the present version of Annex A does not contain the corresponding table of codes.
PrivateCode	INT-U16	PrivateCode is a code specified by the device manufacturer and generally not interoperable between different manufacturers. ENV 13734 uses the term "PrivateOid" in these cases.
OID-Type	INT-U16	Object Identifier Type as defined in nomenclature (do not confuse with ASN.1 OBJECT IDENTIFIER)

Placeholder

Type Placeholder is OCTET-STRING. The user of the format can reserve space for later extensions of the file by placing sufficiently large blocks of null data into certain defined positions in the file by using this data type.

ManufacturerID

Type ManufacturerID is Choice according to following case table. The ISO 8824 object identifier of an organisation can be obtained from a national or international organisation assigning these identifiers.

Name	Cardinality	Type	Tag	Remark
Oid	1	OBJECT-IDENTIFIER	1	ISO 8824 object identifier
Uuid	1	OCTET-STRING	2	ISO 11578 universal unique identifier

Absolute time

Type AbsoluteTime specifies the time of day with at least a resolution of better than one second. Its representation uses the encoding of this abstract data type in the applied encoding rules.

RelativeTime

Type RelativeTime is INT-U32. The Relative Time is a high resolution time definition relative to some event (e.g. a synchronization event at start-up). It is used to position events relative to each other. It is defined as follows: Relative Time has a resolution of 125 us (LSB) which is sufficient for sampling rates up to 8 kHz and spans time periods up to 6.2 days. Unless otherwise specified relative time is measured with respect to the beginning time of the Session Phase Section.

HighResRelativeTime

Type HighResRelativeTime is INT-U64. If either the resolution or the time span of the previously defined Relative Time data type is not sufficient, a High Resolution Relative Time type is defined. The type is defined as follows: 64 bit (8 byte) high resolution time, the LSB represents 1 us. Unless otherwise specified relative time is measured with respect to the beginning time of the Session Phase Section.

ObservationTime

Type ObservationTime is Sequence according to following case table. At least one time representation shall be present of the three alternatives and it is strongly recommended that only one of them is present.

Name	Cardinality	Type	Tag	Remark
Absolutetimestamp	0..1	AbsoluteTime	2448	
Relativetimestamp	0..1	RelativeTime	2449	
Hirestimerelativestamp	0..1	HighResRelativeTime	2537	

SimpleColour

Type SimpleColour is Coded Value according to following code table.

Value	Code	Remark
Colblack	0	RGB=000
Colred	1	RGB=100
Colgreen	2	RGB=010
Colyellow	3	RGB=110
Colblue	4	RGB=001
Colmagenta	5	RGB=101
Colcyan	6	RGB=011
Colwhite	7	RGB=111

ExtNomenRef

Type ExtNomenRef is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Nomenclatureid	1	ExtNomenclatureCode	1	
Nomenclaturecode	1	ANY-DEFINED-BY	2	

PersonNameGroup

Type PersonNameGroup is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Familyname	1	FEFString	1	
Givenname	1	FEFString	2	
Middlename	1	FEFString	3	
Prefix	1	FEFString	4	
Suffix	1	FEFString	5	
Degree	1	FEFString	6	

PersonName

Type PersonName is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Ungroupedname	0..1	FEFString	6001	
Characternamenamegroup	0..1	PersonNameGroup	6002	
Ideographicnamegroup	0..1	PersonNameGroup	6003	
Phoneticnamegroup	0..1	PersonNameGroup	6004	At least one of the groups shall be present. This will be the Characternamenamegroup for European names.

7.3.2 Preamble**7.3.2.1 Encoding of the preamble**

The purpose of the preamble is to identify the file to the programs which read it. Therefore the preamble is one of the few places where the encoding is fixed in this clause. The preamble consists of four 8-byte fields. Figure 11 shows an example of the contents of the preamble.

```

+-----+
· I · "C" · "E" · "N" · <CR> · <LF> · <ctrl-Z> · <EOT> · 84H · I · File-ID
+-----+
· I · "0" · "0" · "0" · "0" · "0" · "1" · "0" · "0" · . . . . . I · Version, here 1.00
+-----+
I · "0" · "0" · "0" · "0" · "0" · "1" · "0" · "0" · . . . . . I · Encoding, here 1.00, ASN.1/BER (Annex B)
+-----+
I · "0" · "0" · "0" · "0" · "0" · "0" · "0" · "0" · . . . . . I · Endianity, here little
+-----+

```

Figure 11 - Example of the Preamble

7.3.2.2 File ID

The first field, File ID, is used to recognise that this file contains vital signs information in a format specified by CEN. The first three bytes are ASCII encoded letters "C" (43H), "E" (45H) and "N" (4EH). They are followed by the ASCII "carriage-return" (13H), line-feed (10H), ctrl-Z (1AH) and "end-of-text" (04H) characters. The last byte in this field contains hex value 84H. The purpose of the last five bytes is to indicate that the file is not corrupted by transmission encoding which, e.g. filters the most significant bit of 8-bit bytes.

7.3.2.3 Version of the Data Format

The second field of the Preamble contains the version of the file exchange format specification. The version number is given in ASCII characters. The first six characters indicate the major version number and the last two characters the minor version number. If the file contains only features specified in version 1.00, the version number shall not be higher than 1.00 in order to make it possible to utilise older versions of the reading software, too.

7.3.2.3 Encoding

The third field contains an 8-byte ASCII string which specifies the encoding rules used in implementing the format. The first six characters indicate the major version of the encoding and the last two characters the minor version of the encoding. If the file contains only features specified in encoding version 1.00, the version number shall not be higher than 1.00 in order to make it possible to utilise older versions of the reading software, too. At present only one encoding is defined, the ASN.1/BER (Abstract Syntax Notation 1, Basic Encoding Rules) encoding in Annex B.

7.3.2.4 Endianity

The last, the fourth field is the endianity field and its length is eight ASCII characters. The ASCII string "00000000" means that the little endian encoding (least significant byte first) is used in multi-byte binary number encoding is used and the ASCII string "00000001" means that big endian encoding (most significant byte first) is used. All the binary number data in the file should be in the same format.³⁾

7.3.3 Session Archive Section

The Session Archive Section is the root type of the abstract syntax defined in this document. The Session Archive Section represents a patient visit or a continuous stay in the a hospital or hospital department. Diagnostic treatments performed during this time period are represented by Session Test Sections contained in the Session Archive.

3) Note that if the ASN.1/BER encoding of Annex B is used, the endianity field here specifies only the endianity of the binary waveform samples in Sample Array Measured Data Block.

7.3.3.1 Section SessionArchiveSection (Tag =7001)

SessionArchiveSection		SAS
1	handle	2337
1	s-archive-id	2507
1	s-archive-name	2513
0..1	s-archive-comments	2530
1	starttime	2538
1	stoptime	2539
0..1	protection	2519
0..1	placeholder	6499
0..1	manufacturerspecific	7002
0..1	healthcareprovider	7003
1	demographics	7004
1..*	sessions	7015
0..*	notes	7016

7.3.3.2 Field handle

Cardinality	Type	Tag	Remark
1	Handle	2337	Unique (within a file) handle

7.3.3.3 Field s-archive-id

Cardinality	Type	Tag	Remark
1	FEFString	2507	

7.3.3.4 Field s-archive-name

Cardinality	Type	Tag	Remark
1	FEFString	2513	

7.3.3.5 Field s-archive-comments

Cardinality	Type	Tag	Remark
0..1	FEFString	2530	

7.3.3.6 Field starttime

Cardinality	Type	Tag	Remark
1	AbsoluteTime	2538	

7.3.3.7 Field stoptime

Cardinality	Type	Tag	Remark
1	AbsoluteTime	2539	

7.3.3.8 Field protection

Cardinality	Type	Tag	Remark
0..1	ArchiveProtection	2519	Archive Protection defines the mechanism used for access control. This mechanism is vendor or implementation specific

Type ArchiveProtection is Sequence according to following field table

Name	Cardinality	Type	Tag	Remark
Protection-type	1	PrivateCode	1	Given by the manufacturer
Protection-key	1	ANY-DEFINED-BY	2	Private implementation

7.3.3.9 Field placeholder

Cardinality	Type	Tag	Remark
0..1	Placeholder	6499	

7.3.3.10 Field manufacturerspecific

Cardinality	Type	Tag	Remark
0..1	ManufacturerSpecificSection	7002	

7.3.3.11 Field healthcareprovider

Cardinality	Type	Tag	Remark
0..1	HealthCareProviderSection	7003	

7.3.3.12 Field demographics

Cardinality	Type	Tag	Remark
1	PatientDemographicsSection	7004	

7.3.3.13 Field sessions

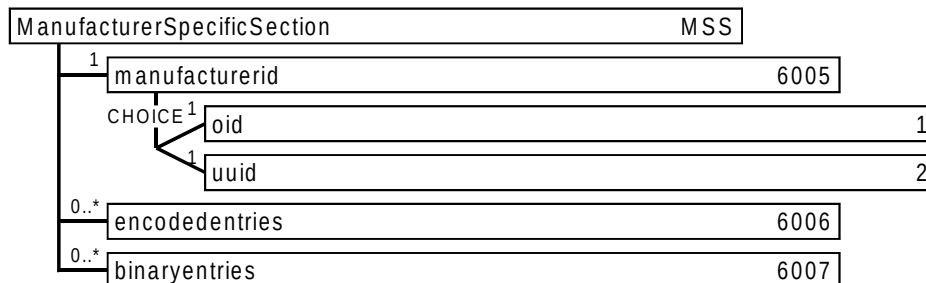
Cardinality	Type	Tag	Remark
1..*	SessionTestSection	7015	

7.3.3.14 Field notes

Cardinality	Type	Tag	Remark
0..*	SessionNotesSection	7016	

7.3.4 ManufacturerSpecificSection (MSS)

7.3.4.1 Section ManufacturerSpecificSection



7.3.4.2 Field manufacturerid

Cardinality	Type	Tag	Remark
1	ManufacturerID	6005	

7.3.4.3 Field encodedentries

Cardinality	Type	Tag	Remark
0..*	ManufacturerSpecificEncoded	6006	

ManufacturerSpecificEncoded

Type ManufacturerSpecificEncoded is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Code	1	PrivateCode	1	
Data	1	ANY-DEFINED-BY	2	Defined by PrivateCode

7.3.4.4 Field binaryentries

Cardinality	Type	Tag	Remark
0..*	ManufacturerSpecificBinary	6007	

ManufacturerSpecificBinary

Type ManufacturerSpecificBinary is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Code	1	PrivateCode	1	
Data	1	OCTET-STRING	2	

7.3.5 HealthCareProviderSection (HPvS)

7.3.5.1 Section HealthCareProviderSection

HealthCareProviderSection		HPvS
1	identification	6008
1	name	6009
0..1	address	6010
0..1	placeholder	6499
0..*	healthcareprofessionals	7008

7.3.5.2 Field identification

Cardinality	Type	Tag	Remark
1	FEFString	6008	

7.3.5.3 Field name

Cardinality	Type	Tag	Remark
1	FEFString	6009	

7.3.5.4 Field address

Cardinality	Type	Tag	Remark
0..1	FEFString	6010	

7.3.5.5 Field placeholder

Cardinality	Type	Tag	Remark
0..1	Placeholder	6499	

7.3.5.6 Field healthcareprofessionals

Cardinality	Type	Tag	Remark
0..*	HealthCareProfessionalSection	7008	

7.3.6 HealthCareProfessionalSection (HPfS)

7.3.6.1 Section HealthCareProfessionalSection

HealthCareProfessionalSection		HPfS
1	handle	2337
	inherited attributes from PersonName	
0..1	identification	6011
0..1	identificationcode	6012
0..1	authorization-level	2481
0..1	function	6048
0..1	functioncode	6049
0..1	placeholder	6499

7.3.6.2 Field handle

Cardinality	Type	Tag	Remark
1	Handle	2337	Unique (within a file) handle

7.3.6.3 Inherited fields from PersonName

The fields of PersonName are included here.

7.3.6.4 Field identification

Cardinality	Type	Tag	Remark
0..1	FEFString	6011	Optional textual unique identification. Corresponds to Physician-id in ENV 13734.

7.3.6.5 Field identificationcode

Cardinality	Type	Tag	Remark
0..1	ExtNomenRef	6012	Optional coded unique identification.

7.3.6.6 Field authorization-level

Cardinality	Type	Tag	Remark
0..1	Authorization	2481	Optional coded unique identification.

Authorization

Type Authorization is Sequence according to following field table.

Name	Cardinality	Type	Tag	Remark
Authorization-type	1	PrivateCode	1	Code from the private range
Authorization-key	1	ANY DEFINED BY authorization-type	2	Organisation specific code etc.

7.3.6.7 Field function

Cardinality	Type	Tag	Remark
0..1	FEFString	6048	Optional textual function specification

7.3.6.8 Field functioncode

Cardinality	Type	Tag	Remark
0..1	ExtNomenRef	6049	Optional coded function specification

7.3.6.9 Field placeholder

Cardinality	Type	Tag	Remark
0..1	Placeholder	6499	

7.3.7 PatientDemographicsSection (PDemS)

7.3.7.1 Section PatientDemographicsSection

PatientDemographicsSection		PDemS
1	handle	2337
0..1	patientid	2394
	inherited attributes from PersonName	
0..1	birthname	2398
0..1	sex	2401
0..1	race	2526
0..1	patienttype	2402
0..1	dateofbirth	2392
0..1	patientgeninfo	2393
0..1	patientage	2520
0..1	gestationalage	2521
0..1	patientheight	2524
0..1	patientweight	2527
0..1	patientbirthlength	2522
0..1	patientbirthweight	2523
0..1	motherpatientid	2504
0..1	mothername	2525
0..1	patientheadcircumference	2490
0..1	patientbsa	2390
0..1	bedid	2501
0..1	diagnosticinfo	2496
0..*	diagnosticcodes	2492
0..1	admittingphysician	2515
0..1	attendingphysician	2516
0..1	dateofprocedure	2518
0..1	proceduredescription	2495
0..*	procedurecodes	2493
0..1	anaesthetist	2479
0..1	surgeon	2532

7.3.7.2 Field handle

Cardinality	Type	Tag	Remark
1	Handle	2337	Unique (within file) handle

7.3.7.3 Field patientid

Cardinality	Type	Tag	Remark
0..1	FEFString	2394	