

Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)

ICS 11.020; 35.240.60

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National foreword

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

This Draft for Development is identical with the European prestandard ENV 12018:1997 *Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)*, prepared by CEN, whose members have committed themselves to making it available in an appropriate form. In the UK the Draft for Development is the form now chosen for ENVs in the information technology area.

This Draft for Development is published under the direction of the Information Systems Technology Assembly, whose Technical Committee IST/35 has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and to keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

NOTE International and European Standards, as well as overseas standards, are available from Customer Services, BSI, 389 Chiswick High Road, London W4 4AL.

After two years this ENV will be reviewed by CEN members with a view to its:

- conversion into a European Standard (which would be implemented in the UK as a British Standard);
- extension once for a further two years;
- replacement by a revised ENV (which would be published in the UK as a revised Draft for Development);
- withdrawal.

The future of this Draft for Development is therefore bound to that of the ENV and the Draft for Development will not be reviewed separately.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the ENV title page, pages 2 to 91 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This Draft for Development, having been prepared under the direction of the DISC Board, was published under the authority of the Standards Board and comes into effect on 15 March 1998

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Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)

Structure des données d'identification, des données administratives et des données médicales communes pour les Dispositifs Connectés par Intermittence utilisés dans le domaine de la santé (y compris les cartes lisibles par machine)

Struktur der Identifizierungs-, Verwaltungs- und der üblichen Medizindaten für im Gesundheitswesen angewandte intermittierend angeschlossene Geräte (einschließlich der maschinenlesbaren Karten)

This European Prestandard (ENV) was approved by CEN on 30 October 1995 as a prospective standard for provisional application.

The period of validity of this ENV 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 ENV can be converted into a European Standard.

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

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CEN

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 “Medical informatics”, the secretariat of which is held by SIS.

This European Prestandard has been prepared under a mandate (BC-IT-217) given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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.

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Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems too. For instance prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible data bases and support systems has led to the development and use of "Healthcare Person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of intermittently connected devices for practical everyday healthcare delivery, the need has arisen for a standardised data format for interchange.

The data carried by an ICD can be categorised in three broad types: identification, administrative and clinical.

Identification data may include:

- identification of the device itself;
- unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include:

- complementary person(s) related data;
- identification of the funding of health care, whether public or private, and their relationships i.e. insurer(s), contract(s) and policy(ies) or types of benefits;
- other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Common clinical data may include:

- items that provide information about health and health events;
- their appraisal and labelling by a Healthcare Provider (HCP);
- related actions planned requested or performed;
- the outcome of such actions (e.g. in terms of tests results).

Because there exists a need to optimise the use of memory by avoiding redundancies, and also because an ICD essentially provides specific answers to definite queries, "high level" Object Modelling Technique (OMT) has been applied with respect to ICDs data structure.

Data in the three categories above share many features. For instance, each may need to include ID numbers, names and dates. Some information may also have clinical as well as administrative uses. Therefore it has been considered inadequate to provide a simple list of items carried by ICDs without applying a generic organisation, based upon the existence of basic data elements. These may be defined by their characteristics (e.g. their format), and from them compound data objects may be constructed; several such objects may also share attributes.

This European Prestandard describes the data objects using plain text in normative clauses 6, 7, and 8. Clause 6 defines basic data objects for referencing.

Clause 7 defines objects for:

- administrative data to allow identification of patient or of healthcare persons (professionals and other types of personnel) and of records belonging to them;
- demographic and general administrative data.

Clause 8 defines objects for clinical data interchange requirements, with special emphasis on coded data. Annex A gives general information about the ASN.1 syntax.

Annex B, Annex C, and Annex D (normative) provide a representation of all objects using ASN.1 notation with the corresponding tags, whilst Annex F provides a data dictionary, and Annex G (informative) an EDIFACT representation of a sample of data objects.

1 Scope

This European Prestandard establishes a common framework for the content and the structure of identification, administrative and common clinical data. It applies exclusively to situations in which such data are recorded on or transported by Intermittently Connected Devices (ICDs) which are intended for use in healthcare.

This European Prestandard specifies the basic structure of the data, but does not specify particular data-sets for storage on devices.

To allow interoperability, whenever an application is built for use in the healthcare domain in compliance with this European Prestandard, data items required for that application shall be drawn from the list of objects (some of which are extensible) as provided in clauses 6 to 8. The detailed functions and mechanisms of the following services are not within the scope of this European Prestandard, (although its structures can accommodate suitable data objects elsewhere specified):

- security functions and related services which are likely to be recommended for ICDs depending on their specific application, for example: confidentiality protection, data integrity protection, and authentication of persons and devices;
- access control services which may depend on active use of some ICD classes such as microprocessor cards;
- the initialisation and issuing process (which begins the operating lifetime of an individual ICD, and by which the ICD is prepared for the data to be subsequently communicated to it according to this European Prestandard).

Data is extracted from an ICD in the form of a “message”. This European Prestandard addresses the “meaning” of the message within or at the interface between an ICD and an application system, not the “method” of its origination or transmission.

The following topics are therefore beyond the scope of this European Prestandard:

- physical or logical solutions for the practical functioning of particular types of ICDs;
- how the message is processed further “downstream” of the interface between two systems;
- the form which data takes for use outside the ICD, or the way in which such data is visibly represented on the ICD or elsewhere.

2 Normative references

This European Prestandard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

ENV 1068:1993, *Medical informatics — healthcare information interchange — Registration of coding schemes*.

EN 1387, *Machine readable cards — Health care applications — Cards: General characteristics*¹⁾.

EN 23166:1994, *Codes for the representation of names of countries*.

EN 27816-3:1992, *Identification cards — Integrated circuit(s) cards with contacts — Part 3: Electronic signals and transmission protocols*.

EN 28601:1992, *Data elements and interchange formats — Information interchange — Representation of dates and times*.

ISO 639:1988, *Codes for the representation of names of languages*.

¹⁾ At present at the stage of draft.

ISO 4217:1990, *Codes for the representation of currencies and funds*.

ISO 5218:1977, *Information interchange — Representation of human sexes*.

ISO 6093:1985, *Information processing — Representation of numerical values in character strings for information interchange*.

ISO 6523:1984, *Data interchange — Structures for the identification of organisations*.

ISO 7498-2:1989, *Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture*.

ISO/IEC 8824:1990, *Information technology — Open Systems Interconnection — Specification of Abstract Syntax Notation One (ASN.1)*.

ISO/IEC 8825:1990, *Information technology — Open Systems Interconnection — Specification of Basic Encoding Rules for Abstract Syntax Notation One (ASN.1)*.

ISO 8859-1:1987, *Information processing — 8-bit single byte coded graphic character sets — Part 1: Latin alphabet No. 1*.

ISO 8908:1993, *Banking and related financial services — Vocabulary and data elements*.

ISO/IEC 9594-8:1990, *Information technology — Open Systems Interconnection: The Directory — Part 8: Authentication framework*.

ISO/IEC 9798-1:1991, *Information technology — Security techniques — Entity authentication mechanisms — Part 1: General model*.

ISO/IEC 10181-2, *Information technology — Open Systems Interconnection — Security Frameworks for Open Systems: Authentication Framework²⁾*.

CCITT, *Numbering plan for the international telephone service*.

Recommendation
E.163

3 Definitions

For the purposes of this European Prestandard, the following definitions apply.

3.1

alternative record identifier

an alternative record identifier is an identifier, composed of characters, that is not identical to the major record identifier and is related to the same record person

3.2

asymmetric authentication method

method for demonstrating knowledge of a secret, in which not all authentication information is shared by both entities

3.3

confidentiality

the property that information is not made available or disclosed to unauthorised individuals, entities or processes. [ISO 7498-2:1989]

3.4

country

the code that identifies the country of origin of the device issuer

NOTE This may not necessarily be the same as the nationality of the device holder.

3.5

cryptographic key

parameter used, in conjunction with an algorithm, for the purposes of validation, authentication, encipherment, or decipherment. [ISO 8908:1993]

²⁾ At present at the stage of draft.

3.6

cryptography

the discipline which embodies principles, means, and methods for the transformation of data in order to hide its information content, prevent its undetected modification and/or prevent its unauthorised use. [ISO 7498-2:1989]

3.7

data integrity

the property that data has not been altered or destroyed in an unauthorised manner [ISO 7498-2:1989]

3.8

data object

a data object is a collection of data that has a natural grouping and may be identified as a complete entity

3.9

data origin authentication

the corroboration that the source of data received is as claimed [ISO 7498-2:1989]

3.10

data sub-object

a data sub-object is a component of a data object that itself may be identified as a discrete entity

3.11

device holder

a device holder is an individual transporting an ICD which contains a record with themselves identified as the major record person

3.12

digital signature

data appended to, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the data unit and protect against forgery e.g. by the recipient [ISO 7498-2:1989]

3.13

entity authentication

the corroboration that an entity is the one claimed [ISO/IEC 9798-1:1991]

3.14

erasure

the process whereby access to a data entity after a given point in time is permanently removed or access denied thereafter to all parties

NOTE This may not involve physical removal from the device, and may merely be the result of altering security such that access is permanently denied to all parties.

3.15

healthcare person device

an HCP device is designed to provide the function of allowing healthcare persons to have their identity and qualifications acknowledged by the information systems that they use, including informatics and telematics, and if necessary, to sign the transactions that they perform via these systems

3.16

ICD application system

an application system that can communicate with an ICD

3.17

ICD connecting unit

a physical device, which may also contain software elements, that enables communication to take place between an ICD and a host

3.18**interface**

may be both physical or electrical or logical. A hypothetical junction between an ICD and the external environment

NOTE This term can be used with a qualifier to describe an attribute to allow data flow to take place over this hypothetical point.

3.19**intermittently connected device (ICD)**

an Intermittently Connected Device:

- a) stores person related information in computer readable format; and
- b) supports data interchange; and
- c) when used for data interchange does not require that the originator of the information receives “confirmation of receipt” of the information”.

NOTE Many different types of hardware may be ICDs but it is important that being an ICD according to this definition is never an intrinsic aspect of the device itself but is dependant upon a certain usage. An ICD may have several uses and hardware functions other than the storage and transmission of person related data.

3.20**linkage**

the ability to join together two or more entities or parts. It may be physical, electrical or relational

3.21**major industry identifier (MII)**

the code that identifies the sector/industry within which the ICD is intended for use

3.22**major record identifier**

the major record identifier is an identifier linked to a primary record relating to a record person within an ICD and a given healthcare delivery system

3.23**personal identification number (PIN)**

the PIN is a 4 to 12 character alphanumeric code or password the device holder possesses for the purposes of authentication

3.24**record**

a record is a collection of data

3.25**record person**

a record person is an individual about whom there is an identifiable record containing person related data

3.26**security**

the combination of confidentiality, integrity and availability

3.27**soft network**

a logical form of linkage in which message sender and recipient are not physically linked and in which message receipt confirmation may not be received by sender

3.28**update**

the process whereby information is erased and replaced by new information

3.29**write**

the process whereby information is added to the ICD

4 Abbreviations

CAD	Card accepting device
HCP	Healthcare person
HCD	Healthcare coding scheme designator
ICC	Integrated circuit card
ICD	Intermittently Connected Device
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
PIN	Personal Identification Number
MII	Major Industry Identifier
UTC	Coordinated Universal Time

5 Basic data object model for an ICD

5.1 Object structure

A set of basic data object tools has been designed to facilitate the storage of identification, administrative, or common clinical data in a flexible structure, allowing for future and application specific enhancements. These tools should help implementation of common accessory characteristics of stored data in a way that allows efficient use of memory, an important feature for many ICDs.

The tools consist of a genetic data structure based on an object-oriented model. The content of this object-oriented structure is described in Annex B (normative) using ASN.1 notation. The ASN.1 notation is only used as a tool to describe this structure. Examples of an implementation using EDIFACT syntax are also provided in Annex G (informative).

NOTE It is possible to take the data objects and recombine them whilst preserving their context specific tags, and to define new objects, while still preserving interoperability.

In addition to the capability of building complex aggregate data objects from simpler building blocks, the standard allows for associations between certain objects, so that information can be shared. This feature is mainly used to allow, for example, a set of accessory attributes to be used as services to several stored information objects.

The basic data object tools consist of these functional groups:

- a) identification, security and linkage objects consisting of:
 - record persons,
 - device specific data,
 - coding schemes used,
 - healthcare persons and sites,
 - accessory attributes,
 - linkages;
- b) administrative data objects consisting of:
 - administrative coded data,
 - function related non coded administrative data sets;
- c) clinical data objects consisting of:
 - coded clinical data,
 - non coded clinical data,
 - function related clinical data.

5.2 Linking

A number of objects in the data model of this European Prestandard are used mainly as a reference to other objects. One example is the *RecordPerson* that defines the basic identification information of a person to whom records on the device relate. Since this is a part of an aggregate object containing information on all record persons in a sequential order, the pointer may be a simple one-dimensional integer number. This type of pointer has the name *RecPersPointer* and is used extensively to indicate the record person to whom a certain information object is related.

In other situations, constructed objects contain a more general pointer called a *RefPointer* that is a sequence of tags allowing a reference to any object, including sub-objects that can only be referenced as part of a constructed object, using an application specific tag and a number of context specific tags to sufficient depth.

A *RefPointer* to the name of a healthcare person may contain the following information with the appropriate tags (here represented by their symbolic names):

HealthCarePersons [7]HealthCarePerson no 7 [1] HcpName
Application tag Context level 1 Context level 2

All administrative and clinical *Coded* data items have *Accessory attributes*. These data objects contain information on when, where and who recorded data. They allow specification of security services and parameters. If security requirements permit, such data objects may be associated with several objects. There is also a third possibility that allows the creation of linkages between all objects using the *Linkages* object (see further in clause 11.4). This is an ordered list of link associations. All entries in this list are a sequential list of other objects, each defined with a *RefPointer*.

EXAMPLE: Link no 2 may link four objects

- 1:
- 2: *RefPointer*₁ *RefPointer*₂ *RefPointer*₃ *RefPointer*₄
- 3:

An example of this process could be the linkage of the following objects as defined in clause B.20.

Diagnosis	— <i>RefPointer</i> ₁
MedicationPrescription	— <i>RefPointer</i> ₂
MedicationNote	— <i>RefPointer</i> ₃
MedicationDispensed	— <i>RefPointer</i> ₄

This linkage table entry may be pointed to by the *ClinRefPointer* of each *ClinDat* object.

NOTE Even though the *Link* object itself is openly available, the linked objects may have restricted access.

6 Basic data objects for referencing

6.1 Overview

A series of generally useful type definitions have been made that have no meaning by themselves, but which are used to define other objects within this standard. These objects are described in clause 6.2.

A series of basic data objects have also been defined to be used as references in other information objects for both administrative and clinical data. Contrary to the above, some of these objects are also used directly, particularly when identification is the primary use of the ICD. Operations that may be performed with these objects in association with other information objects are described in clause 6.3.

6.2 Generally useful types used for implicit definitions

These objects shall only be used to define other objects and shall never be referenced independently.

The OCTET STRING type used in the following definitions shall be used to represent character strings coded in the ISO 8859-1:1987 character set unless otherwise specified.

6.2.1 Person name related data objects

Data objects related to person names shall be constructed as defined textually according to a top-down approach in the following sub-clauses.

The ASN.1 representation of all these person name related data objects is provided in Annex B, clause **B.1.1**.

6.2.1.1 The “Full Name” data object

The object “Fullname” shall consist of a sequence of “Title”, “Surname Prefix”, “Surnames”, “Surname Suffix”, and “Forenames”.

The ASN.1 representation of these data sub-objects is provided in Annex B, clause **B.1.1**.

6.2.1.2 The “Title” data object

The object “Title” shall consist of an octet string of length from 1 to 7 characters.

6.2.1.3 The “Surname Prefix” data object

The object “SurnamePrefix” shall consist of an octet string of length from 2 to 15 characters.

6.2.1.4 The “Surnames” data object

The object “Surnames” shall be constructed of a sequence of up to two objects “Surname”; one “Surname” may be designated as the “Preferred Surname”.

6.2.1.5 The “Surname” data object

Each object “Surname” shall be constructed according to the definition contained in object “Nameelement” as defined in clause **6.2.1.8**.

6.2.1.6 The “Forenames” data object

The object “Forenames” shall consist of a sequence of up to three objects “Forename”; one “Forename” may be designated as the “Preferred Forename”.

6.2.1.7 The “Forename” data object

Each object “Forename” shall be constructed according to the definition contained in object “Nameelement” as defined in clause **6.2.1.8**.

6.2.1.8 The “Name Element” data object

The object “Nameelement” shall consist of an octet string of length 2 to 27 characters.

6.2.2 Address and telecommunication related data objects

Data objects related to address locations and data objects related to telecommunications shall be constructed as defined textually according to a top-down approach in the following sub-clauses. The ASN.1 representation of all these address and telecommunication related data objects is provided in Annex B, clause **B.1.2**.

6.2.2.1 The “Postal Address” data object

“PostAddr” data object shall not include the post code nor a component identifying the country and shall consist of an alphanumeric string of variable length between 1 and 35 characters.

The structure of such an address shall follow the format: House name/Number and name of street, Town, County. The separator * (asterisk) shall be used between each component. In the event of only one component being present the separator shall precede this component.

The ASN.1 representation of this data object is provided in Annex B, clause **B.1.2**.

6.2.2.2 The “Post Code” data object

“PostCode” data object shall consist of an alphanumeric string of variable length between 1 and 8 characters.

6.2.2.3 The “Country” data object

Country shall be represented by coded data in the form of a three character numeric string as defined in EN 23166:1994.

6.2.2.4 The “Date” data objects

“Date” data objects shall be constructed according to the UTC time definitions detailed in ISO/IEC 8824:1990, with a length of between 6 and 12 characters.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.1.2**.

6.2.2.5 The “Place” data object

“Place” data objects shall be constructed as an octet string with a length comprised between 1 and 15 characters.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.1.2**.

6.2.2.6 The “Telecommunication” data object

The data object “Telecom” shall consist of a set of optional data objects “TelnoRecpersonHome” (Telephone Number of Record Person’s Home), “TelnoRecpersonWork” (Telephone Number of Record Person’s Working place), “TelnorecpersonOther” (Other Telephone Number of Record Person), “FaxnoRecpersonHome” (Fax Number of Record Person’s Home), “FaxnoRecpersonWork” (Fax Number of Record Person’s Working place), “X.400address”, and “OtherNetworkAddress”.

With the exception of “X.400address”, and “OtherNetworkAddress” data objects, each of these objects shall be constructed according to the definition contained in object “Telno” (see clause **6.2.2.7**).

“X.400address”, and “OtherNetworkAddress” data objects shall be constructed according to the definition contained in clause **6.2.2.8**.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.1.2**.

6.2.2.7 The “Telephone Numbers” data object

A “Telno” data object shall be constructed in the format required to dial the number from any location in the world. It shall not include either the code required to obtain an international line from any specific location, nor the first redundant character of any internal area code.

The string shall therefore consist of country code consisting of 1-3 digits as described in CCITT Recommendation E. 163 Annex A, area code and local telephone number. Such telephone numbers shall consist of a numeric string with no separators of between 1 and 15 characters.

The ASN.1 representation of this data object is provided in Annex B, clause **B.1.2**.

6.2.2.8 The “X.400” and “Other Network Addresses” data objects

“X.400” and “OtherNetworkAddress” shall consist of an octet string of between 1 and 30 characters in length.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.1.2**.

6.2.2.9 The “Money” data object

The “Money” data object shall be constructed as a sequence of both value (“Amount”) and “Currency”.

“Amount” shall consist of an integer.

“Currency” shall be in the form of a code as described in ISO 4217:1990, i.e. in the form of an octet string with a length of three characters.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.1.3**.

6.3 Basic data objects

Basic data objects are objects that contain information in relation to the device itself, or otherwise used for reference to other objects.

6.3.1 Record persons

This series of data objects provide identification information regarding the various persons that may have records on the device.

Usually there will only be data relating to one person.

6.3.1.1 The “Record Persons” data object

This is identification information regarding the various persons that may have records on the device. When the device is a card, there will usually be data relating to only one person.

The “RecordPersons” data object shall consist of a sequence of “RecordPerson” data objects. A “Major Record Person” shall always be designated. In addition there may be any number of other Record Persons. Thus the “Major Record Person” shall be followed by a choice of other Record Persons (spouse, child, father, mother, other person). Each of these “RecordPerson” data objects shall be constructed as defined in clause 6.3.1.2.

The ASN.1 representation of these data objects is provided in Annex B, clause B.2.1.

NOTE When the device is a card, the Major Record Identifier of the Major Record Person, is also the Major Identifier for the device; in such a case it will therefore always be present as visible data on the outside of the card.

6.3.1.2 The “Record Person” data object

The purpose of this object is to allow for record linkage to be performed. The object may also be used to provide identification information. When the device is a card, the major record identifier of the major record person will always be present as visible data on the outside of the card if following the scheme standardised within EN 1387.

The “Record Person” data object shall consist of a set of a “Major Record Identifier”, of optional “Alternative Record Identifiers”, and of a “Record ID Verification” data objects.

The ASN.1 representation of these data objects is provided in Annex B, clauses B.2.1 to B.2.4.

6.3.1.3 The “Major Record Identifier” data object

The “Major Record Identifier” data object shall be constructed as a sequence of components. These components shall consist of the Major Industry Identifier (MII), the issuer country, the issuer identifier, a check digit, and a record ID number.

The healthcare sector indicator (“Major Industry Identifier”, or MII) shall consist of a 2 characters long Numeric String. The default value shall be 80 as already allocated to the health sector.

The “Issuer Country” code shall be three characters numeric coded data as defined according to EN 23166:1994 in clause 6.2.2.3 (“Country” data object).

The “Issuer Identifier” shall be a five character numeric code as allocated to all card issuers when the ICD is in the form of a card. This issuer code shall be allocated by a nationally appointed registration authority. A “Check Digit” shall be calculated on the foregoing three code values according to the Luhn modulus ten double-add-double check digit formula.

The “Record ID Number” shall be constructed according to the “Evolutionary Record Identifier” data object defined below. The evolutions of the record identifier are intended to provide for the existence of any format of identifier whilst preserving the migration of identifiers towards integrated systems.

A “Record ID Number” shall consist of:

- a transitional sequence identifier consisting of a single integer defined as an “Evolutionary Record Identifier”. This data object indicates the phase of evolution of the numbering system and value. Thus identifiers can appear in three possible types. But all such record ID numbers when undergoing future structural change shall transfer to the all numeric format;

- the “Evolutionary Record Identifier” data object shall consist of a choice of three octet strings (Evolution1, Evolution2, and Evolution3).

“Evolution1” type defines a free format alphanumeric record identifier, with any form of separator, and a maximum number of characters of 27.

“Evolution2” type defines a record identifier that has only alphanumeric characters and a single form of separator being a forward slash (/). Its maximum number of characters is 27.

“Evolution3” type defines a RecordIdentifier that is all numeric with no separators and a maximum number of characters of 27.

NOTE 1 The evolutions of the RecordIdentifier are intended to provide for the existence of any format of Identifier whilst preserving the migration of identifiers towards integrated systems. These evolutions are “tagged” and thus identified, so that records relating to an individual may be identified by more than one type of identifier within a given healthcare delivery system. This concept is distinct from the facility provided within alternative record identifiers (see clause 6.3.1.4).

NOTE 2 In the case of an ICD in the form of a card the Evolutionary Record Identifier shall be the card holder identification number as defined in EN 1387.

The ASN.1 representation of this data object and its components is provided in Annex B, clause B.2.2.

6.3.1.4 The “Alternative Record Identifiers” data object

Alternative record identifiers provide for the function of record linkage and are intended for use between different healthcare delivery systems or where more than one record identifier exists.

The “Alternative Record Identifiers” data object shall be constructed as an optional set consisting of a social security number and a sequence of alternative numeric record identifiers.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.2.3**.

6.3.1.5 The “Record Identification Verification” data object

The “Record Identification Verification” data object represents data that are fixed for the lifetime of the record person to whom the record relates. It is to be used as an aid to verification when identity is not obvious.

The “Record Identification Verification” data object shall be constructed as a set consisting of the record person full name as written at birth registration, his or her date of birth, the sex of the individual as stated at birth, his or her place of birth described in a concise format, and optionally accessory attributes.

The “Record Person Name” shall be defined as a “FullName” data object (see **6.2.1.1**).

The “Date of Birth” shall be defined as a “Date” data object (see **6.2.2.4**).

The “Sex at Birth” shall consist of an size 1 octet string according to ISO 5218:1977.

The “Place of Birth” shall be defined as a “Place” data object (see **6.2.2.5**).

The “Accessory Attributes” data object is defined in clause **6.3.5**.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.2.4**.

6.3.2 The “Device Specific Data” object

Device specific data gives information related to the capabilities of the device, the types and ranges of information stored. Additional data shall exist within the object to enable signature functions related to the device to take place.

The object “DeviceData” shall consist of the set of optional sub-objects “DevType”, “DevDirectory”, and “DevIdentification” as defined in clauses **6.3.2.1** to **6.3.2.7**.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.3.5**.

6.3.2.1 The “Device Type” data object

The “DevType” data object shall contain a set of coded data that will convey information regarding the type of ICD and its capabilities. It shall not contain information regarding either applications on the device or specific security attributes. The object “DevType” shall consist of a set of three Coded Data objects (constructed as defined in clause **6.3.4.2**), namely “Device Class”, “Device Standard”, and “Device Specifications”.

The ASN.1 representation of this data object is provided in Annex B, clause **B.3.2**.

6.3.2.2 The “Device Class” data object

The “DeviceClass” data object shall be in the form of coded data and shall specify the class of ICD.

6.3.2.3 The “Device Standard” data object

The “DeviceStandard” data object shall be in the form of coded data and shall specify a particular published standard in relation to the class of device.

6.3.2.4 The “Device Specifications” data object

The “DeviceSpec” data object shall be in the form of coded data and shall specify the functions that the device is able to perform and its capabilities.

6.3.2.5 The “Device Applications” data object

The applications on the device may be defined by two methods. Broad classes (identification, administrative, clinical, and other) may be defined in the boolean object “DevApplicationClass”, while a more specific definition may be added using coded data in the “DevApplicationCodes” object.

Thus the “DevApplications” data object, listing the applications on the device, shall consist of a set of sub-objects “DevApplicationClass” and “DevApplicationCodes”.

Sub-objects “DevApplicationClass” are of Boolean type; “True” means “available”; combinations are allowed.

The “DevApplicationCodes” object shall consist of a set of coded data objects as defined in clause 6.3.4.2. The ASN.1 representation of these data objects is provided in Annex B, clause B.3.3.

6.3.2.6 *The “Device Specific Directory” data object*

The application specific tags of the objects stored on the device shall be contained in a separate object that will be unprotected by any subsidiary security functions. This data object shall consist of a set of reference tags (RefTag) related to the addressable objects available on the device. It shall not convey any other meaning.

The object RefTag is defined in clause 6.4.2.

The ASN.1 representation of this data object is provided in Annex B, clause B.3.4.

6.3.2.7 *The “Device Identification” data object*

The object “Devidentification” shall provide the identification of the individual device and the various parties involved in its manufacturing and issuing. It shall consist of coded data to represent the device manufacturer, coded data to represent the device component manufacturer, coded data to represent the personaliser of the device, a unique device serial number and the issuing date of the device.

The object “DevIdentification” shall be constructed as a set of sub-objects “deviceManufacturer”, “deviceComponentManuf”, “devicePersonaliser”, deviceIdNo”, and “deviceActivationDate”.

The objects “deviceManufacturer”, “deviceComponentManuf”, and “devicePersonaliser” shall consist of CodedData objects, as defined in clause 6.3.4.2.

The object “deviceIdNo” shall consist of an octet string with a length comprised between 1 and 21 characters.

The optional object “deviceActivationDate” shall consist of a Date object, as defined in clause 6.2.2.4 above.

The ASN.1 representation of these data objects is provided in Annex B, clause B.3.5.

6.3.3 *Objects linking sites and persons*

6.3.3.1 *The “Healthcare Sites” data object*

The “Health Care Sites” data object shall consist of a reference table of sites which are associated with healthcare personnel who have recorded data on the device.

The “HealthCareSites” data object shall be constructed as a sequence of the sub-object “HeathCareSite”.

This data object “HealthCareSite” itself shall be constructed as a set of sub-objects “hcsCountry” (of “Country” type), “hcsId” (a numeric string with a length of between 8 and 21 characters), “hcsName” (an octet string of 15 characters), “hcsAddr” (of “Address” type), “hcsType” (CodedData), and “hcsTelecom” (of “Telecom” type).

The ASN.1 representation of these data objects is provided in Annex B, clause B.4.

6.3.3.2 *The “Healthcare Persons” data object*

The “Healthcare Persons” data object shall contain a list of all healthcare persons (professionals and type of personnel that have performed healthcare) recorded on the ICD or added data to it.

The “HealthCarePersons” data object shall consist of a sequence of the sub-object “HealthCarePerson”.

The data object “HealthCarePerson” itself shall be constructed as a set of “hcpCountry” (of “Country” type), “hcpIdNo” (a numeric string with a length between 1 and 21 characters), “hcpName” (of “Fullname” type), optionally “hcpRelationCode” (of “CodedData” type, a code that would indicate things like primary responsible general practitioner, specialist, consultant, etc.), “hcpClass” (a sequence of booleans described hereafter), optionally “hcpProfession” (a sequence of “hcpProfCode”, in order to allow for national codes linking to exact definitions of various HCP groups), optionally “hcpEmploymentNo” (of BitString type), optionally “hcpEmploymentData” (a sequence of “CodedData”).

The object “hcpClass” shall consist of a sequence of booleans indicating professions (doctor, dentist, pharmacist, midwife, nurse, admin., professions allied to medicine, professions allied to dentistry, professions allied to pharmacy, professions allied to nursing).

The ASN.1 representation of these data objects is provided in Annex B, clause B.5.

6.3.3.3 *Linking of sites and healthcare persons: the “Site Mix Table” data object*

The “SiteMixTable” data object provides the function of allowing multiple HCPs to be present at one site or one HCP to be present at multiple sites without having the necessity of having duplicated data.

The “SiteMixTable” data object shall consist of a sequence of “SiteMix” objects, each consisting of “HCSRef” and “HCPRef” reference pointers pointing respectively at “HealthCareSites” and “HealthCarePersons”.

The ASN.1 representation of these data objects is provided in Annex B, clause **B.6**.

6.3.4 Coded data

Coded values are understood by reference to the coding scheme to which they apply. The general principle in this European Prestandard is that it is not mandatory to use a particular coding scheme, **unless specified within this European Prestandard**, when such codes act as parameters. One example is the use of EN 23166:1994 for country codes.

When a coding scheme is exclusively specified within this European Prestandard no alternative coding scheme shall be allowed. Any references to coding schemes not so specified may however be modified in the future independent of the rest of the standard.

6.3.4.1 The “CodingSchemesUsed” data object

Coding schemes not specified within this European Prestandard may themselves be the subject of a registration within the coding schemes procedure as defined in ENV 1068:1993 and shall then be interpreted, if at all, in accordance with all conditions of that registration.

ENV 1068:1993 specifies a procedure for registration of coding schemes and the allocation of a healthcare coding scheme designator (HCD). It is possible to reference both internationally registered coding schemes and unregistered coding schemes as defined in clause 5 of ENV 1068:1993. The use of such private CodeIdentifiers may however create the potential risk of ambiguity if a device should be used in an open environment.

Code values from unregistered schemes (or registered schemes outside the scope of a particular application) cannot be understood, unless the recipient of information is party to an agreement with the originator to use additional or non registered coding schemes.

The data object “CodingSchemesUsed” shall consist of an ordered sequence of the sub-object “CodingScheme”, which shall itself consist of a code identifier (an octet string of 6 characters), a code length (of integer type), and an optional free text comment (an octet string with a length of between 1 and 20 characters).

The ASN.1 representation of this data object is provided in Annex B, clause **B.7.1**.

6.3.4.2 The “CodedData” data object

The data object “CodedData” shall include both a reference to coding schemes used and a code data value as well as optional free text and shall be constructed as a set of the sub-objects “codingSchemeRef”, “codeDataValue”, and optionally “codeDataFreeText”.

The object “codingSchemeRef” is a Ref Pointer pointing at a value that identifies a particular coding scheme within the object coding schemes used. If CodingSchemeRef = 0 then the coding scheme is implicit in this standard.

The data type “codeDataValue” has been defined to indicate the actual code value in a particular coding Scheme. The length of “codeDataValue” is one OCTET and the following codeDataValues are defined: “A” means “Administrative free text entry”, “C” means “Clinical free text entry”.

The ASN.1 representation of this data object is provided in Annex B, clause **B.7.2**

6.3.5 Attributes

6.3.5.1 Accessory attributes

The data object “AccessoryAttributes” shall consist of an ordered set of data that is essential to record an audit trail regarding both the originator of the information and the means via which it arrives to the recipient. It shall consist of:

Date1 which shall represent the time/date of data being communicated to the ICD across the interface;

Date2 which shall represent the time/date of data being available to the originator of the message;

Place1 which shall represent the identity/locator of the sender of the message and is linked with “person1”;

Place2 which shall represent the identity/locator of the original author of the data;

Personid3 shall be either the code or representation of the person/device/system that provided the information that was added to a system to become the data within the “message”;

SecurityLevels which shall be constructed according to the ASN.1 definition contained in **B.8** and shall represent the rights in relation to reading, writing, updating and erasing the data contained within the data object to which these accessory attributes are attached.

CompressionMethodData shall be constructed according to the ASN.1 definition contained in **B.8** and shall consist of a ref pointer pointing at a defined compression methodology within a compression methodology table. This represents the methodology applied to the data contained within the data object to which the accessory attributes are attached.

Object security attributes.

The “AccessoryAttributes” data object shall be constructed as a set of the following optional data objects:

- “date1” and “date2” (of “Date” type);
- “place/Person1” and “place/Person2” (of “RefPointer” type);
- “personId3” (a set of “PersonCode” of RefPointer type, and free “PersonText” with a length of up to 30 characters);
- and of “ObjectSecAttributes” (a set of “SecurityServices”).

The data objects “SecurityServices” shall each consist of a sequence of digital signatures, as well as algorithms and keys for signature and encryption.

None of the above attributes is mandatory, however all are highly desirable. It is recommended that all (with the possible exception of Personid3) should be delivered every time that the media/system allows. A list of priorities in groupings follows and in principle should be followed as groups:

```
{Date1,Date2,Place1,Place2,Personid3,SecurityLevels, CompressionMethodData,ObjSecAttributes}
{Date1,Place1,Place2, SecurityLevels, CompressionMethodData,ObjSecAttributes}
{Date1,Place1,Place2, SecurityLevels, CompressionMethodData,ObjSecAttributes}
{Date1,Place2, SecurityLevels, CompressionMethodData,ObjSecAttributes}
{Date1, SecurityLevels, CompressionMethodData,ObjSecAttributes}
{SecurityLevels, CompressionMethodData,ObjSecAttributes}
{ObjSecAttributes}
```

NOTE This “AccessoryAttributes” data object can be associated to any other data object.

The ASN.1 representation of this data object is provided in Annex B, clause **B.8**.

6.3.5.2 Device and data security attributes

Data stored in intermittently conected devices in health care may be personally sensitive. For this reason this European Prestandard provides a series of security attributes in the form of data objects that may be required for the provision of security functions. The actual data content (value) is not within the scope of this standard, nor are the mechanisms that make use of these data elements. It is emphasised that the security attributes cannot satisfy given security requirements without the implementation of the appropriate security functions and mechanisms within the ICD.

- | | |
|--------|--|
| READ | <ul style="list-style-type: none"> — Always — Never — Protected — With ICD holders’ agreement — With external authentication (for instance: card issuer, health care professional, ...) — In relation to the originator only |
| WRITE | <ul style="list-style-type: none"> — Protected — With ICD holders’ agreement — With external authentication — Never |
| UPDATE | <ul style="list-style-type: none"> — Protected — With external authentication — With ICD holders’ agreement — In relation to the originator only — Never |

- ERASE — Protected
 — With external authentication
 — With ICD holders agreement
 — In relation to the originator only
 — Never

Following these principles a matrix of possibilities represents data access conditions:

		PROTECTED			
	ALWAYS	HOLDER AGREEMENT	EXTERNAL AUTHENTICATION	ORIGINATOR ONLY	NEVER
READ					
WRITE					
UPDATE					
ERASE					

Such rights of “access” are attributable to specific individuals with respect to discrete data items. These rights will be defined by application developers and can be controlled by automated systems such as health care professional cards. The rights may be defined at the application level thereby providing application and potential country specificity.

The “SecurityServices” data object provides for the storage of data required to deliver these security functions and mechanisms. These data can be “attached” to individual data elements thereby preserving the original author’s security requirements when the data object is transferred between different forms of ICD. This mechanism may therefore ensure that in the process of transferring data from active to passive media and then back to active media, the original security requirements are re-generated. This ability also allows exact replication of an ICD such as on regeneration after failure.

6.4 Link associations between objects

The following reference objects may be associated with other information objects defined. This relation is a not an aggregation. The reference object is not a part of the information object but stays independent and may be referenced by several objects.

The concept used within this European Prestandard is to reference (point at) the appropriate record person as well as a healthcare provider and relevant accessory attributes.

These linkages add value to the data and may be used to provide context specificity.

6.4.1 The “RecordPersonPointer” data object

The data object “RecPersPointer” is used to reference one of the record persons stored in the “RecordPersons” data object and shall be of integer type.

The ASN.1 representation of this data object is provided in Annex B, clause **B.9.1**.

6.4.2 The “ReferencePointer” and “ReferenceTag” data objects

A general reference pointer is defined in this European Prestandard as an ordered list of tags pointing to the object or sub-object that is referenced.

The data object “RefPointer” shall consist of a sequence of “RefTag” (of integer type).

The “RefTag” is the APPLICATION SPECIFIC tag of the object as defined in this European Prestandard. The following “RefTag” specify the CONTEXT SPECIFIC tags in increasing depth.

The ASN.1 representation of this data object is provided in Annex B, clause **B.9.2**.

6.4.3 The “Linkages” data object

The “Linkages” object is used to create linkages between any objects. It shall be constructed as a sequence of sub-objects “Link”.

The data object “Link” shall consist of a sequence of references to other objects in the form of a sequence of “RefPointer” objects. This is pointed to by a “LinkagePointer” object.

The ASN.1 representation of this data object is provided in Annex B, clause **B.9.3**.

6.5 Data from ICDs held by healthcare persons

Data objects from ICDs held by healthcare persons shall provide for the functions of identification, access control and signature. These functions are provided by a discrete number of sub-objects.

The identification information related to a healthcare person and his or her responsible agency shall be provided by the data object “HcpData”. This “HcpData” data object shall be constructed as an implicit sequence of health care person identification data, of healthcare site location data, and of optional accessory attributes.

The ASN.1 representation of this data object is provided in Annex B, clause **B.10**.

7 Basic identification and administration data

This clause defines a number of identification and administrative data objects that are always associated with a record person as defined in clause **6**.

7.1 The “Variable Identification Data” object

The variable identification data object shall consist of a sequence of identification data that relates to the respective record person in the record persons object.

The “VariableIdData” object shall be constructed as a sequence of “RecPersVariableID” data objects.

The “RecPersVariableID” data object shall consist of a set of the following optional sub-objects:

- “Address” (of “Address” type);
- “PreviousAddresses” (a sequence of “Address”);
- “Telecom” (of “Telecom” type);
- “Preferred Languages” (of “CodedData” type);
- “MaidenName”, “PreviousSurname”, and “OtherNames” (of “Surname” type as defined in **6.2.1.4**);
- and “AccessoryAttributes” (see clause **6.3.5**).

The ASN.1 representation of this data object is provided in Annex B, clause **B.11**.

7.1.1 The “Address” data object

The “Address” data object shall not include the elements of data used to represent either the post code or country. It shall consist of two components:

- an object containing data that used in combination with both the post code and country code shall represent the internationally agreed form of postal address (“PostAddr”, an octet string with a length of between 1 and 35 characters);
- an optional object containing data that is location specific that is appropriate for the purposes of healthcare, being an extension of the basic postal address (“ExtHcCareAddr”, an octet string with a length of between 2 and 175 characters).

NOTE Within the data string a standard separator of star (*) shall be utilised which shall be appended to the start of the successive data element. In some applications this may produce the physical effect of line feed. This separator shall be present before the last data element even if there is only a single element.

The ASN.1 representation of this data object is provided in Annex B, clause **B.11.1**.

7.1.2 The “Record Person Telecom” data object

The “RecordpersonTelecom” data object is of “Telecom” type as defined in clause **6.2.2.6**.

The ASN.1 representation of this data object is provided in Annex B, clause **B.11.2**.

7.1.3 The “Preferred Languages” data object

The record person preferred languages object shall allow for up to four languages spoken and/or understood in a sequence determining the order of preference. Languages shall be coded according to ISO 639:1988.

The “PreferredLanguages” data object shall be constructed as a sequence of up to four “Language” sub-objects in order of preference, each language being designated by a proper code (i.e. an octet string with a length of three characters).

The ASN.1 representation of this data object is provided in Annex B, clause **B.11.3**.

7.1.4 The “Maiden Name” data object

The “Maiden Name” data object shall contain a sub-object “Surnames” that represents the name of the individual prior to marriage.

It shall be constructed as a set of sub-object “MaidenSurname” (of “Surnames” type), and optional “AccessoryAttributes” (as defined in clause 6.3.5).

The ASN.1 representation of this data object is provided in Annex B, clause B.11.4.

7.1.5 The “Previous Surnames” data object

The “Previous Surnames” data object shall contain a sub object as defined in “Surnames” that represents the surname of the individual prior to the one in current usage.

It shall be constructed as a set of sub-object “PreviousSurname” (of “Surnames” type as defined in clause 6.2.1.4), and optional “AccessoryAttributes” (as defined in clause 6.3.5).

The ASN.1 representation of this data object is provided in Annex B, clause B.11.5.

7.1.6 The “Other Names” data object

The “OtherNames” data object shall contain a set of sub objects as defined in “Fullname” that represent the different names that records identified and linked with this individual may contain.

It shall be constructed as a set of sub-object “OtherSurname” (of “Fullname” type, as defined in clause 6.2.1.1 above), and optional “AccessoryAttributes” (as defined in clause 6.3.5).

The ASN.1 representation of this data object is provided in Annex B, clause B.11.6.

7.2 The “Record Person Post Code” data object

The “PostCode” data object shall be a separate object from “Address”. It may thus be software manipulated to different positions in printed/visually represented data according to local environment rules. It may also be used for other purposes than mailing to indicate roughly the location of residence, e.g. for epidemiological purposes.

The object “RecPersPostCode” shall be constructed as a set of “PersPostCode” (of “PostCode” type, as defined in clause 6.2.2.2), and “PostcodePointer” (of “RecPersPointer” type, as defined in clause 6.4.1).

The ASN.1 representation of this data object is provided in Annex B, clause B.12.

7.3 The “Record Person Country” data object

The “RecPersCountry” data object shall be a separate object from “Address”. It may thus be software manipulated to different positions in printed/visually represented data according to local environment rules. It may also be used for other purposes than mailing to indicate roughly the location of residency.

The “RecPersCountry” data object shall be constructed as a set of “PersCountry” (of “Country” type, as defined in clause 6.2.2.3), and “PersCountryPointer” (of “RecPersPointer” type, as defined in clause 6.4.1).

The ASN.1 representation of this data object is provided in Annex B, clause B.13.

7.4 The “Contact Persons” data object

The “ContactPersons” data object shall contain data relating a sequence of “persons to contact in emergency” in relationship to an individual, in order of preference, with a possibility of indicating the relationship in a free text comment.

The “ContactPersons” data object shall be constructed as a set of sub-objects “ContactPerson” and “RecPersPointer” (the latter of “RecPersPointer” type, as defined in clause 6.4.1).

The “ContactPerson” object shall itself consist of a set of sub-objects “Name” (of “Fullname” type, as defined in clause 6.2.1.1), “ContactTelno” (of “Telecom” type, as defined in clause 6.2.2.6), and optionally “Comment” (an octet string with a length of up to 20 characters).

The ASN.1 representation of this data object is provided in Annex B, clause B.14.

7.5 The “Record Person Visiting Instructions” data object

The function of this object, which may have separate security attributes from the other objects, is to convey information that is not contained in either the object PostalAddress or ExtHCAAddress to aid a healthcare worker arrive at a physical location, e.g. “even though its number1 Marston Crescent the entrance is actually round the back in Windsor Square”.

The “RecPerVisitInstr” data object shall contain data that adds value to an address. This shall be a separate object with a pointer to the address to which it relates.

The “RecPerVisitInstr” data object shall be constructed as a set of sub-objects “visitInstr” (an octet string with a length of up to 80 characters), “visitPointer” (of “RecPersPointer” type as defined in clause 6.4.1), and optional “AccessoryAttributes” (as defined in clause 6.3.5).

The ASN.1 representation of this data object is provided in Annex B, clause B.15.

7.6 The “Payment Provisions” data object

The “Payment provisions” data object shall cover a generic term that will include both insurance schemes and national or other public healthcare payment systems.

There may be several instances of “Payment provisions” each of them with one payment body, which is the term used to include insurance companies and other organisations which pay for healthcare delivery.

There may be a number of policies for each payment body. The policy conditions can cover several persons, each with a set of conditions.

As an example the information contained in this object allows the storage of the information stated on the official E 111 document held by any EU citizen travelling outside his/her member state (though within EU) as enacted within Article 22 1(a) Council Regulation 1408/71.

The “PaymentProvisions” data object shall consist of a sequence of sub-objects “PaymentProvision”.

The “PaymentProvision” data object shall itself consist of a set of sub-objects:

- “PaymentBodyID”;
- optionally “PaymentBodyName” (an octet string with a length of up to 20 characters), “PaymentBodyAddress” (a sequence of “Address”, “PostCode”, and “Country” as defined in clauses 6.2.2.1 to 6.2.2.3, and “PaymentBodyTelecom” (of “Telecom” type, as defined in clause 6.2.2.6).
- “Policies”;
- and optionally “AccessoryAttributes” (as defined in clause 6.3.5).

The “PaymentBodyID” data object shall consist of a sequence of sub-objects “PaymentBodyCountry” (of “Country” type as defined in clause above), and “PaymentBodyNumber” (an octet string with a length comprised between 1 and 9 characters). “PaymentBodyCountry” represents the country of the payment body number; the country of address may be different.

The “Policies” data object shall consist of a set of sub-objects “Policy”.

The “Policy” data object itself shall consist of a set of sub-objects “PolicyIdNo” (an octet string with a length of up to 21 characters), “Member” (optional, an octet string with a length of up to 15 characters), and “CoveredPersonConditions” (a set of sub-objects “PersonCondition”); the term “condition” is to be understood in the sense of “conditions of cover” and not “medical condition”.

The “PersonCondition” data object shall consist of a sequence of sub-objects “RecPersPointer” (as defined in clause 6.4.1), and “Condition”.

The “Condition” data object shall itself consist of a sequence of the following sub-objects:

- “ObligatoryStatus” (optional, boolean, “true” meaning “obligatory”);
- “CareCoverageCode” (optional, a set of “CoverageCode” of “CodedData” type as defined in clause 6.3.4.2); CoverageCode will include (but is not limited to) surgical care, accident, occupational disease, occupational accident, pregnancy, long term disease;
- “CareCoverageText” (optional, an octet string with a length of up to 20 characters);
- “CoverageAreas” (optional, a set of “CoveredCountries”, being themselves of “Country” type as defined in clause 6.2.2.3);
- “PaymentLevel” (a sequence defined hereafter);
- “StartDate” (optional, of “Date” type as defined in clause 6.2.2.4);
- “EndDate” (optional, of “Date” type as defined in clause 6.2.2.4);
- “AccessoryAttributes” (optional, as defined in clause 6.3.5).

The “PaymentLevel” data object shall consist of a sequence of optional sub-objects:

- “LowerLimitCoverage” (of “Money” type), the value above which provisions are valid;
- “UpperLimitCoverage” (of “Money”), the value under which provisions are valid;

- “BenefitsRate” (of “real” type), percentage of coverage;
- “SetPrice” (of “boolean” type, “true” means a SetPrice fixed for the service);
- “SetPriceValue” (of “Money” type);
- “ThirdParty” (of “boolean” type, “true” means the payment body pays directly);
- “EmploymentStatus” (a set of optional boolean sub-objects “Employed”, “SelfEmployed”, “EmployedPensionable”, and “SelfEmployedPensionable”, “true” means status applicable according to EU E111 form);
- “AuthorisationReq” (of “boolean” type, “true” means authorisation by payer required).

The ASN.1 representation of this data object is provided in Annex B, clause **B.16**.

7.7 The “Patient Payments” object

The “PatientPayments” data object shall contain data related to the fees actually paid by the patient for healthcare services recorded on the device.

It shall be constructed as a set of sub-objects “IdPatientPayment” (of “RecPersPointer” type), “PatientAccPayment” (of “Money” type), “PatientCarePayments” (a sequence of sub-objects “PatientCarePayment”, each consisting of a set of “ProcedureRef” of “RefPointer” type, a pointer to the procedure that was paid for, and of “ProcedureAmount” of “Money” type), and optionally “AccessoryAttributes” (as defined in clause 6.3.5).

The ASN.1 representation of this data object is provided in Annex B, clause **B.17**.

7.8 The “Other Coded Administrative Data” object

This object shall make possible the use of any particular coding system permitted by the application, as registered under the registration system described by ENV 1068:1993, as described in clause 6.3.4.

The “OtherCodedAdminData” data object shall consist of a sequence of sub-objects “AdmDat”.

The “AdmDat” data object itself shall consist of a set of sub-objects “IDPatientCodedData” (of “RecPersPointer” type), “AdmCodedData” (of “CodedData” type), “AdminMoney” (of “Money” type), “AdmRefPointer” (of “LinkagePointer” type, a pointer to the “Link” element in the “Linkages” reference table), and optionally “AccessoryAttributes” (as defined in clause 6.3.5).

The ASN.1 representation of this data object is provided in Annex B, clause **B.18**.

8 Clinical data

This generic model for the storage of clinical data follows the same general structure as the storage of coded administrative data as described above.

8.1 The “Clinical Coded Data” object

The “ClinicalCodedData” data object shall be constructed as a sequence of sub-objects “ClinDat”.

The “ClinDat” data object shall consist of a set of sub-objects “IDPatientCodedData” (of “RecPersPointer” type), “ClinCodedData” (of “CodedData” type), “Parameter” (a choice of optional data objects to be defined and described in clause 8.2), “ClinRefPointer” (of “LinkagePointer” type, a pointer to the “Link” element in the “Linkages” reference table), and optionally “AccessoryAttributes” (as defined in clause 6.3.5).

The ASN.1 representation of this data object is provided in Annex B, clause **B.19**.

8.2 The “Parameter” data objects

The “Parameter” data objects are designed to be attached to a “ClinicalCodedData” data object, and by their content they add value to that coded data. The “Parameter” data objects are distinct and their content vary dependant upon their function: they define a structure and a set of rules related to this content.

8.2.1 The “Medication Note” parameter object

A “Medication Note” parameter object shall consist of a set of coded data consisting of:

- “GenericMedCode”, coded data that shall represent the GENERIC name of the medicine as distinct from either its proprietary or chemical name (e.g. ATC code);
- “ProprietaryMedCode”, coded data that shall represent the proprietary name of the medicine;
- “DosageInstructionsCode”, coded data that shall represent the dosage instructions;

“PatientAdviceCode”, coded data that shall represent general advice regarding the medicine to be conveyed to the patient.

NOTE The “ClinCodeData” object itself can also specify the literal proprietary name.

The ASN.1 representation of this data object is provided in Annex B, clause **B.20.1**.

8.2.2 The “Medication Prescription” parameter object

A “Medication Prescription” parameter object shall consist of a set of coded data consisting of:

“GenericMedCode”, coded data that shall represent the GENERIC name of the medicine as distinct from either its proprietary or chemical name (e.g. ATC code);

“ProprietaryMedCode”, coded data that shall represent the proprietary name of the medicine;

“Strength”, a sequence of “NoStrengthUnits” of Real type, and “StrengthUnits” of coded data, that shall represent the number of units and the nature of the units used to measure the strength of the medicine;

“Form”, coded data that shall represent the form of a medicine;

“DosageInstructionsCode”, coded data that shall represent the dosage instructions;

“PatientAdviceCode”, coded data that shall represent general advice regarding the medicine to be conveyed to the patient;

“Iterations”, a numeric string that shall have the default value of 1 and shall represent the number of times the quantity may be dispensed;

“QuantityToDispense”, a set of “DaysSupply” (of numeric string type), “NoDispenseUnits” (of real type), and “DispenseUnits”, a choice of several boolean type objects (“TabletCaps” including suppositories, vagitories and other forms of special “tablets” that may be sold as an arbitrary number of individual entities, “Packages”, “Grams”, “Milligrams”, “Litres”, “Millilitres”, “IntlUnits”, and “Special”);

“ReimbursementInfo”, coded data that shall represent information about the level of reimbursement of the considered medicine.

NOTE The “ClinCodeData” object itself can specify the specific proprietary name and also form, strength and package amount. In this case the specially tagged objects for this information may be omitted.

The ASN.1 representation of this data object is provided in Annex B, clause **B.20.2**.

8.2.3 The “Medication Administered” parameter object

A “Medication Administered” parameter object shall consist of a set of coded data consisting of:

“GenericMedCode”, a code that represents the GENERIC name of the medicine as distinct from either its proprietary or chemical names (e.g. ATC code);

“ProprietaryMedCode”, coded data that shall represent the proprietary name of the medicine;

“Strength”, a sequence of “NoStrengthUnits” of Real type, and “StrengthUnits” of coded data, that shall represent the number of units and the nature of the units used to measure the strength of the medicine;

“Form”, coded data that shall represent the form of a medicine;

“DosageInstructionsCode”, coded data that shall represent the dosage instructions;

“PatientAdviceCode”, coded data that shall represent general advice regarding the medicine to be conveyed to the patient;

“QuantityAdministered”, a set of “NoDispenseUnits” (of real type), and “DispenseUnits”, a choice of several boolean type objects (“TabletCaps” including suppositories, vagitories and other forms of special “tablets” that may be sold as an arbitrary number of individual entities, “Packages”, “Grams”, “Milligrams”, “Litres”, “Millilitres”, “IntlUnits”, and “Special”).

“BatchIdentifier” (of Octetstring type), optional, to identify the production batch to which the medication belongs to.

NOTE The “ClinCodeData” object itself can specify the specific proprietary name and also form, strength and package amount. In this case the specially tagged objects for this information may be omitted.

The ASN.1 representation of this data object is provided in Annex B, clause **B.20.3**.

8.2.4 The “Medication Dispensed” parameter object

A “Medication Dispensed” parameter object shall consist of a set of “MedicationDispensedActual” that shall itself consist of:

a code that represents the actually dispensed medicine. This may be given in two forms, the specific code similar to the ClinCodeData of a prescription note or by “GenericMedCode”, a code that represents the GENERIC name of the medicine as distinct from either its proprietary or chemical names (e.g. ATC code);

“ProprietaryMedCode”, coded data that shall represent the proprietary name of the medicine;

“Strength”, a sequence of “NoStrengthUnits” of Real type, and “StrengthUnits” of coded data, that shall represent the number of units and the nature of the units used to measure the strength of the medicine;

“Form”, coded data that shall represent the form of a medicine; form and strength need only to be present if it differs from original prescription;

“DosageInstructionsCode”, coded data that shall represent the dosage instructions: this item shall only be recorded if dosage is different from the linked prescription;

“PatientAdviceCode”, coded data that shall represent general advice regarding the medicine to be conveyed to the patient: this item shall only be recorded if advice is different from prescription;

“QuantityDispensed”, a set of “NoDispenseUnits” (of real type), and “DispenseUnits”, a choice of several boolean type objects (“TabletCaps” including suppositories, vagitories and other forms of special “tablets” that may be sold as an arbitrary number of individual entities, “Packages”, “Grams”, “Milligrams”, “Litres”, “Millilitres”, “IntlUnits”, and “Special”).

“DispenseByID” (of “HcpRefPointer” type as defined in clause above), data to enable the identification of the dispensing agency;

“DispenseDate” (of “Date” type as defined in clause above), to identify the date when the medicine has been dispensed;

“DispensePrice” (of “Money” type), optional data to identify the cost of the medicine;

“DispensePaid” (of “Money” type), optional data to identify the price the patient actually paid to receive the dispensed medicine.

“DispensingIdentifier” (of “Octectstring” type), optional: where the application requires additional checks for certain classes of drugs (e.g. narcotics) this identifier indicates for reconciliation purposes quantities supplied to, delivered by, the pharmacist.

“BatchIdentifier” (of Octectstring type), optional, to identify the production batch to which the medication belongs to.

The ASN.1 representation of this data object is provided in Annex B, clause **B.20.4**.

8.2.5 The “Drug Sensitivity” parameter object

A “Drug Sensitivity” parameter object shall indicate that the record person is allergic to the product represented by the coded data. It shall consist of CodedData used to represent the sensitivity type i.e. “rash” and optional free text.

The ASN.1 representation of this data object is provided in Annex B, clause **B.20.5**.

8.2.6 The “Laboratory Test Results” parameter object

A “Laboratory Test Results” parameter object shall consist of a set of “Results” sub-objects appropriate to the information imparted by the code to which it is attached.

The “Results” object shall contain data that presents:

“TimeSample” (UTC time), the time of collection of the sample;

“LabResult” (of “LabValue” type as defined hereafter), the laboratory value of the result;

“NormalRange” (of boolean type, “true” meaning “normal” and “false” meaning “therapeutic interval”), data to record the reference range of the laboratory;

“RefLowerLimit” (of “LabValue” type as defined hereafter), optional;

“RefUpperLimit” (of “LabValue” type as defined hereafter), optional.

The “LabValue” type shall be defined as a set of “Units”, coded data that represent the units of measurements, and of “Value” (of real type).