

Machine readable cards — Healthcare applications — Logical data structures and concepts for different card technologies for use by patients in health applications

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National foreword

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**Machine readable cards - Healthcare applications - Logical data
structures and concepts for different card technologies for use
by patients in health applications**

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Foreword

This document has been prepared by CEN /TC 224, "Machine readable cards, related device interfaces and operations".

This CEN Report is published to provide availability of the work undertaken by CEN/TC 224 during the years 1992-1997 which was aiming to produce a European standard entitled "Machine readable cards – Healthcare applications – Logical data structures and concepts for different card technologies for use by patients in health applications". CEN/TC 224 has decided to close its own work towards completing this standards work being convinced that the work effort should be concentrated and will be better continued in ISO/TC 251 "Health informatics".

The scope of the work presented herein was intended to provide solutions for different types of storage technologies although the focus of interest in Europe has been the possibilities offered by Integrated Circuit Cards. This CEN Report describes an important approach towards providing a solution where, with certain constraints, the same structure of information objects could be provided for different technologies facilitating the integration of card applications with various health related applications using databases and network communication in addition to the information stored on cards.

The work of CEN/TC 224 started in parallel with CEN/TC 251, to a large extent with the same experts. CEN/TC 251 received a mandate from EU and EFTA and developed the ENV 12018 entitled "Medical informatics – Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)" which was adopted in 1997. This standard is currently undergoing a major revision in preparation for being transferred to a European Standard.

This CEN Report is largely based on ENV 12018 and contains large parts of this standard. The reason for including those initially was that as it had not been finalized, it could not safely be referenced. During the completion of this CEN/TC 224 work a few amendments compared to ENV 12018:1997 were included and provide one of the inputs to the revision of ENV 12018.

This CEN Report is also being presented to ISO/TC 215 and it is expected that the basic ideas and many details will be able to provide the basis for one or very likely several International Standards on this topic.

It is important to understand that the specification provided in this CEN Report although expressed as normative requirements, is not a European Standard.

Introduction

This CEN report contains details regarding the standardization of logical data storage to be utilised in conjunction with machine readable cards intended for use by patients within health applications.

Data objects have been defined within ENV 12018:1997 that, with respect to fitness of purpose, had similar attributes and thence fitted a common data storage potential such as is encompassed by a dedicated file (DF) as described within a smart card.

This strategy has a number of advantages, the most important being that the "master file" containing the data objects with all their sub components can be transmitted and thence stored as a single super object within media lacking processing capability. However for media with processing capabilities such objects can be subdivided into different logical files as described above and re-assembled on transmission.

Because of the technological limitations of some types of media it is necessary that some data transformation take place when transferring data between some different types of technologies. However, as the interface devices to these technologies are dissimilar the software interface will always be aware of the technology with which it is interfacing and therefore able to perform these transformations. This approach to logical data storage can enable the storage of all types of information theoretically on any type of device and does away with the redundancy produced by the common core approach. In the case of some media (in particular ISO compatible magnetic stripe media) it is expected that the interface will carry out transformation of the data when transferring it between different card technologies (to cope with differential encoding rules and the application of ASN.1 context specific tags).

1 Scope

This CEN Report specifies the logical data storage format for data in machine readable cards to be used by patients in health applications.

The data structures and the methodology are described in plain text and ASN.1 notation.

This CEN Report is not applicable to bar coded data on machine readable cards.

2 Normative references

This CEN Report 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 CEN Report only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1387:1996, *Machine readable cards – Health care applications – Cards : General characteristics*.

EN 1867:1997, *Machine readable cards – Health care applications – Numbering system and registration procedure for issuer identifiers*.

EN ISO 3166-1:1997, *Codes for the representation of names of countries and their subdivisions – Part 1 : Country codes (ISO 3166-1:1997)*.

EN ISO/IEC 7811-2:1996, *Identification cards – Recording technique – Part 2 : Magnetic stripe (ISO/IEC 7811-2:1995)*.

EN ISO/IEC 7812-1:1995, *Identification cards – Identification of issuers – Part 1 : Numbering system (ISO/IEC 7812-1:1993)*.

EN ISO/IEC 7816-4:1996, *Information technology - Identification cards – Integrated circuit(s) cards with contacts – Part 4 : Interindustry commands for interchange (ISO/IEC 7816-4:1995)*.

EN ISO/IEC 7816-5:1995, *Identification cards – Integrated circuit(s) cards with contacts – Part 5 : Numbering system and registration procedure for application identifiers (ISO/IEC 7816-5:1994)*.

EN ISO/IEC 7816-6:1997, *Identification cards – Integrated circuit(s) cards with contacts – Part 6 : Interindustry data elements (ISO/IEC 7816-6:1996)*.

ENV 12018:1997, *Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)*.

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

ISO 639-2:1998, *Code for the representation of names of languages – Part 2 : Alpha-3 code*.

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

ISO/IEC 7816 (all parts), *Identification cards – Integrated circuit(s) cards with contacts*.

ISO/IEC 8824 (all parts), *Information technology – Abstract Syntax Notation One (ASN.1)*.

ISO/IEC 8825 (all parts), *Information technology – ASN.1 encoding rules*.

ISO/IEC 10118-2:1994, *Information technology – Security techniques – Hash-functions – Part 2 : Hash-functions using an n-bit block cipher algorithm*.

3 Terms and definitions

For the purposes of this CEN Report, the terms and definitions given in ISO/IEC 7816, ISO 7498-2:1989, ISO/IEC 8824:1990 and ISO/IEC 10118-2:1994 and the following apply.

3.1

health professional card (HPC)

an Health Professional Card (HPC) 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

3.2

application system

an application system that can communicate with machine readable card

3.3

connecting unit

a physical device which may also contain software elements that enables communication to take place between a machine readable card and a host or application system

3.4

interface

may be both physical or electrical or logical. An hypothetical junction between a machine readable card 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.

3.5

linkage

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

3.6

major industry identifier (MII)

the code that identifies the sector/industry within which the machine readable card is intended for use

3.7

dedicated file (DF)

a file containing 'AC' and allocable memory. It may be parent of elementary files and/or dedicated files

3.8

directory

general name for MF or DF

3.9

elementary file (EF)

a file containing 'AC', data or program. An EF cannot be parent of another file

3.10

file

a number of bytes with a certain structure

3.11

file identifier

each file (MF,DF,EF) has a file identifier consisting of 2 bytes

3.12

master file

the mandatory unique file representing the root of the file structure and containing 'AC' and allocable memory. It may be parent of dedicated files and/or elementary files

4 Symbols and abbreviated terms

ASN.1	Abstract Syntax Notation One
DF	Elementary file
HPC	Health professional card
MF	Master file
PDC	Patient data card
S	Data type : simple
C	Data type : constructed
M	Data status : mandatory
O	Data status : optional
AID	Application identifier
RID	Registered application provider identifier
PIX	Proprietary application identifier extension
ICC	Integrated circuit card
IC	Integrated circuit
IIN	Issuer identification number
MII	Major industry identifier
ID	Identifier
MRI	Major record identifier

5 Notations

'O' to '9'	Hexadecimal characters
'A' to 'F'	Hexadecimal characters
OCTETSTRING	A string of octets whose representation is defined within ISO 8859-1.

6 Logical model

This CEN Report describes the logical storage of data on differing technological types of machine readable cards for use by patients within the healthcare sector.

6.1 Existing data structures

In order to look at the issue of logical data structures it is important to look at specific uses of portable records and their existing data structures and functionality. This to some extent requires data set identification, at least at the functional level, and ENV 12018:1997 determines these requirements.

The structures defined within ENV 12018:1997 provide for a logical data structure which is based upon a composition of data objects. These objects are described as ASN.1 structures and allocated individual tags to provide for identification and data manipulation. Such a structure lends itself to intercompatibility of storage between media types.

6.2 Logical data structures

ENV 12018:1997 provides concise definitions for data elements that may need to be transmitted and stored on PDCs and HPCs using ASN.1 notation. The strategy employed in the structure of these data objects allows them to be function related and to have the possibility of shared common security attributes. The standard allows for optionality in respect to the data to be transmitted and stored and as such some information is mandated by this document in order to preserve functionality. The implication of this is that as the data storage capabilities of the machine readable card technology degrades so does the “quality, content and potential value” of the data.

The overall principle is that the logical data storage on the device should take the form of a “Master file”, which is subdivided into a number of “directories” referenced by an application specific tag each of which contains the elemental files holding data elements.

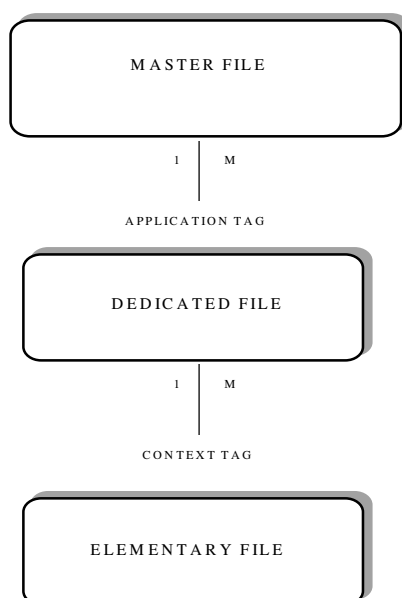


Figure 1 — Data model

The data is organised in a consistent format echoed around the consistency of these file structures. Because the data is both transmitted and stored as ASN.1 type objects both the tag and size of the objects are contained within the file.

6.3 Encoding and storage of ASN.1 objects

The encoding and eventual storage of the ASN.1 objects shall be as described within the normative media specific annexes A,B and C.

6.4 Storage of non-standardized data

If it is technologically possible this standard provides a method to store non-standardized data, the methodology being defined within the appropriate technology dedicated annex.

7 Data definitions

Data shall be stored in files with the data elements constructed in accordance with ENV 12018:1997 and the ASN.1 definitions described hereafter.

NOTE Only those data objects that are enhanced by additions to the data objects contained in ENV12018:1997 are represented hereafter.

7.1 "HealthCareData" data object

The global data stored on a healthcare card is defined as a global object using ASN.1 syntax as below

```
HealthCareCardData ::= SET
{
    DeviceData                [0]          SET,
    CardHolderData            ['67']        SET,
    HealthCarePersons          ['6C']        SET OPTIONAL,
    HealthCareSites            ['68']        SET OPTIONAL,
    SiteMixTable               ['6F']        SET OPTIONAL,
    CodingSchemesUsed          ['6A']        SET OPTIONAL,
    Linkages                   ['6B']        SET OPTIONAL,
    PatientData                [7]          SET OPTIONAL,
    HealthCareProfData         ['6D']        D SET OPTIONAL,
    HealthCareWorkerData       ['6E']        SET OPTIONAL
}
```

NOTE Not all applications will necessarily require all the 18 data objects specified within this standard.

On a patient data card, the data object PatientData shall be present and shall be mandatory.

```
PatientData [4] SET OPTIONAL
{
    AdminDat                [0]          SET OPTIONAL,
    ClinCodedDat             ['7B']        SET OPTIONAL
    LimEmergencyData         ['7A']        SET OPTIONAL
}
```

AdminDat	[0]	SET	
{			
VariableIDData	['4B']		SEQUENCE OF RecPersVariableID OPTIONAL,
RecPersPostCode	['4C']		SET OPTIONAL,
RecPersCountry	['4D']		SET OPTIONAL,
ContactPersons	['78']		SET OF ContactPerson OPTIONAL,
RecPersVisitInstr	['72']		SET OPTIONAL,
PaymentProvisions	['50']		SEQUENCE OF PaymentProvision OPTIONAL,
PatientPayments	['71']		SET OPTIONAL,
OtherCodedAdminData	['70']		SEQUENCE OF AdmDat OPTIONAL
}			

7.1.1 The "DeviceData" data object

DeviceData	::= SET	
{		
Devtype	['60']	OPTIONAL,
DevApplications	['62']	OPTIONAL,
DevDirectory	[2]	OPTIONAL,
DevIdentification	[3]	OPTIONAL,
PatientDevSecurity	['69']	OPTIONAL
HCPDevSecurity	['66']	OPTIONAL
}		

7.1.2 The "DevDirectory" data object

DevDirectory	[2]	::= SEQUENCE
{		
TagAllocationAuthority	['79']	SEQUENCE,
ApplicationIdentifiers	['61']	SET OF ApplicationIdentifier OPTIONAL
}		

ApplicationIdentifier	['61']	::= SEQUENCE
{		
AID	['4F']	CodedData
		Application Identifier
ApplicationLabel	['50']	OCTETSTRING (SIZE(1..16)) OPTIONAL,
Path	['51']	OCTETSTRING (SIZE(2..126)) OPTIONAL,
		Even values only allowed
CommandToPerform	['52']	OCTETSTRING (SIZE(4..127)) OPTIONAL,
DiscretionaryData	['52']	OCTETSTRING (SIZE(1..127)) OPTIONAL,
		Relevant data or ASN.1 objects defined by application provider
Application Template	['73']	OCTETSTRING (SIZE(3..127)) OPTIONAL
		ASN.1 objects relevant to the application
}		

7.1.3 Identification of card issuers and registered application providers

EN ISO/IEC 7816-5:1995 defines the following mechanism for the identification of card issuers and registered application providers.

The AID contained within the DevDirectory data object refers to either a card issuer or a registered application provider.

The first digit of the AID indicates the registration category (see Table 1).

Table 1 — Registration categories

First digit of the AID	Registration category
'0' - '9'	Issuer identification number (as defined in EN ISO/IEC 7812-1:1995) '8x' indicates telecommunications and other future industry assignments '80' indicates Health Care
'A'	Registered Application Provider (International registration)
'B'	Reserved for ISO
'C'	Reserved for ISO
'D'	Registered Application Provider (National registration)
'E'	Reserved for ISO
'F'	Proprietary (non-registered)

If the AID refers to a card issuer it has the following format (2 to 16 bytes) :

- INN ('80' -country code-national registration number) ;
- Separator = 'FF' ;
- PIX OPTIONAL.

NOTE Separator is mandatory if PIX is present.

If the AID refers to an (RID) it has the following format (2 to 16 bytes) :

- RID (10BCD, first digit = 'A' or 'D') ;
- PIX (0 to 11 bytes) OPTIONAL.

Some data types are common and used in several data objects being either administrative or clinical (as is the data type RefTag described in the previous clauses). This subclause defines the structures of these common data types.

7.1.3.1 The "DevIdentification" data object

The "DevIdentification" data object contains information about the full card production and the card issuing process.

DevIdentification [3] ::= SEQUENCE

```

{
  DevManufData          ['64'] SEQUENCE OPTIONAL,
                        Information relative to card production
  DevComponentData      ['63'] SEQUENCE OPTIONAL,
                        Information relative to component production
  DevIssuerData          ['65'] SEQUENCE
                        Information relative to card issuing
}
```

7.1.3.2 The "DevManufData" data object

The "DevManufData" data object contains information about the production of card.

DevManufData	['64'] ::= SEQUENCE OPTIONAL	
{		
DevManufId	[0]	CODEDDATA OPTIONAL, Card embedder Identification
DevNumber	[1]	INTEGER (SIZE 6) OPTIONAL, Card identification defined by manufacturer
IccCharacteristics	[2]	INTEGER (SIZE 6) OPTIONAL, Card characteristics relative to card issuing
IccTranskeyRef	[3]	INTEGER (SIZE 1) OPTIONAL Reference of transportkey between embedder and card personalisator (issuing process)
}		

7.1.3.3 The "DevComponentData" data object

The "DevComponentData" data object contains information about the production of component.

DevComponentData	['63'] ::= SEQUENCE OPTIONAL	
{		
ComponentManufId	[0]	CODEDDATA OPTIONAL, Component manufacturer Identification
ComponentNumber	[1]	INTEGER (SIZE 6) OPTIONAL, Component serial number
ComponentType	[2]	OCTET STRING (SIZE(1..10)) OPTIONAL, Component type defined by manufacturer
ComponentTranskeyRef	[3]	INTEGER (SIZE 1) OPTIONAL Reference of transportkey between component manufacturer and embedder
}		

7.1.3.4 The "DevIssuerData" data object

The "DevIssuerData" data object contains information about the card issuer and issuing process.

DevIssuerData	['65'] ::= SEQUENCE																			
{																				
CardIssuerIdentifier	[0]	SEQUENCE, Identification of card issuer																		
CardId	[1]	NUMERIC STRING (SIZE(10)) Card identification defined by issuer																		
CardType	[2]	CodedData IMPLICIT { <table> <tr> <td>Patient Data Card</td><td>[0]</td><td>BOOLEAN,</td></tr> <tr> <td>HC-Professional card</td><td>[1]</td><td>BOOLEAN,</td></tr> <tr> <td>HC-Worker card</td><td>[2]</td><td>BOOLEAN,</td></tr> <tr> <td>HC-Service-card¹⁾</td><td>[3]</td><td>BOOLEAN,</td></tr> <tr> <td>Test card</td><td>[4]</td><td>BOOLEAN,</td></tr> <tr> <td>Duplicate</td><td>[5]</td><td>BOOLEAN.</td></tr> </table> True ==> duplicate card False ==> principal card	Patient Data Card	[0]	BOOLEAN,	HC-Professional card	[1]	BOOLEAN,	HC-Worker card	[2]	BOOLEAN,	HC-Service-card ¹⁾	[3]	BOOLEAN,	Test card	[4]	BOOLEAN,	Duplicate	[5]	BOOLEAN.
Patient Data Card	[0]	BOOLEAN,																		
HC-Professional card	[1]	BOOLEAN,																		
HC-Worker card	[2]	BOOLEAN,																		
HC-Service-card ¹⁾	[3]	BOOLEAN,																		
Test card	[4]	BOOLEAN,																		
Duplicate	[5]	BOOLEAN.																		
CardEffDate	[3]	HCPDate OPTIONAL,																		
CardExpDate	[4]	HCPDate OPTIONAL,																		
	[5]	AccessoryAttributes OPTIONAL																		
}																				

1) Card containing cryptographic keys, playing a role in key-management, for internal use of domain authorities. The holder is an application authority (it can be a "department card" shared by several authorities).

The boolean values for HC-Professional, HC-worker and HC-Service shall be set to null in a patient data card.

7.1.3.5 The "CardIssuerIdentifier" data object

The "CardIssuerIdentifier" data object corresponds to the Line 1 (mandatory in accordance with EN 1387:1996) of the front of an healthcare card.

CardIssuerIdentifier ::= SEQUENCE				
{				
IIN	[0]	NUMERIC STRING (SIZE(10)) ²⁾		
		MI	NUMERIC STRING (SIZE(2)),	DEFAULT '80'
		Country	NUMERIC STRING (SIZE(3))	IssuerCountry code
		Identifier	NUMERIC STRING (SIZE(5))	IssuerIdentifier
Checkdigit	[1]	NUMERIC STRING (SIZE(1)) OPTIONAL		
		Calculated in accordance with Luhn		
}				

7.1.3.6 The "CardHolderData" data object

The "CardholderData" data object defines the personal characteristics of the card holder.

CardHolderData ::= SET				
{				
MRI	[0]	SEQUENCE, -- card holder MRI as defined in ENV 12018:1997		
HolderName	[1]	Fullname (SEQUENCE) OPTIONAL, -- defined in ENV 12018:1997		
PreferredLanguages	[2]	SEQUENCE SIZE(0..4) OF HCLanguage OPTIONAL, up to 4 language codes in order of preference		
	[3]	AccessoryAttributes OPTIONAL		
}				
		HCLanguage	::= OCTET STRING (SIZE(2 or 3))	
			If size = 2 : language coded in accordance with ISO 639:1988	
			If size = 3 : language coded in accordance with ISO 639-2:1998	

8 Data encoding and manipulation rules

- 8.1** Data shall be encoded to machine readable cards in accordance with the rules specified in the normative technology specific annexes A, B, and C.
- 8.2** Where data is transferred between cards of differing technologies the mandatory data elements prescribed by this document shall persist. If it is not technologically possible to transmit the all mandatory elements then the choice of mandatory elements to be transmitted is defined within the technology dependent annexes.
- 8.3** The application specific tags specified in Table 1 below shall be applied to the ASN.1 data objects specified above and within ENV12018:1997 when stored in dedicated files or equivalents.
- 8.4** The data object HCP data is not utilised within a PDC.

2) EN ISO 3166-1:1997.

Table 2 — Application specific tags and their values

RecordPersons	'45'
DeviceData	'46'
HealthCareSites	'68'
HealthCarePersons	'6C'
SiteMixTable	'6F'
CodingSchemesUsed	'6A'
VariableIdData	'4B'
RecPersPostCode	'4C'
RecPersCountry	'4D'
ContactPersons	'78'
RecPersVisitInstr	'72'
PaymentProvisions	'50'
PatientPayments	'71'
OtherCodedAdminData	'70'
Linkages	'6B'
ClinicalCodedData	'7B'
LimEmergencyData	'7A'
HcpData	'56'