INTERNATIONAL STANDARD

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Health informatics — Patient healthcard data —

Part 3: Limited clinical data

Informatique de santé — Données relatives aux cartes de santé des patients —

Partie 3: Données cliniques limitées

Reference number
ISO 21549-3:2004(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21549-3 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 21549 consists of the following parts, under the general title *Health informatics — Patient healthcard data:*

— *Part 1: General structure*

— *Part 2: Common objects*

— *Part 3: Limited clinical data*

— *Part 4: Extended clinical data*

— *Part 5: Identification data*

— *Part 6: Administrative data*

— *Part 7: Electronic prescription (medication data)*

— *Part 8: Links*

At the time of publication of this part of ISO 21549, some of these parts were in preparation.

This work is being carried out by ISO/TC 215 in collaboration with CEN/TC 251, *Medical informatics*, under the Vienna Agreement, with ISO having the lead role. This new series of International Standards is intended to replace the European Prestandard ENV 12018 ratified by CEN in 1997.

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 records, 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. 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 data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized into three broad types: identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given healthcare data card *de facto* has to contain device data and identification data and may in addition contain administrative and clinical data.

Device data is defined to include:

— identification of the device itself;

— identification of the functions and functioning capabilities of the device.

Identification data may include:

— 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-related data;

— identification of the funding of healthcare, 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.

Clinical data may include:

— items that provide information about health and health events;

— their appraisal and labelling by a healthcare person (HCP);

— related actions planned, requested or performed.

Because a data card essentially provides specific answers to definite queries, whilst at the same time there is a need to optimize the use of memory by avoiding redundancies, a “high-level” object-modelling technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

This part of ISO 21549 describes and defines the limited clinical data objects used in or referenced by patient-held health data cards using UML, plain text and abstract syntax notation (ASN.1).

It does not describe or define the common objects defined within part 2 of this International Standard, even though they are referenced and utilized within this document.

Health informatics — Patient healthcard data —

Part 3: Limited clinical data

1 Scope

This part of ISO 21549 describes and defines the limited clinical data objects used in or referenced by patient-held health data cards using UML, plain text and abstract syntax notation (ASN.1).

It is applicable to situations in which such data are recorded on or transported by patient healthcards whose physical dimensions are compliant with those of ID-1 cards as defined by ISO/IEC 7810.

This part of ISO 21549 specifies the basic structure of the data contained within the data object limited clinical data, but does not specify or mandate particular data-sets for storage on devices. In particular, the data contained within the data objects in limited clinical data are intended to aid the delivery of emergency care, but are by themselves neither intended, nor suitable, for the provision of all the information required.

The detailed functions and mechanisms of the following services are not within the scope of this part of ISO 21549 (although its structures can accommodate suitable data objects specified elsewhere):

— the encoding of free text data;

— security functions and related services which are likely to be specified by users for data cards, depending on their specific application, for example confidentiality protection, data integrity protection, and authentication of persons and devices related to these functions;

— access control services which may depend on active use of some data card classes such as microprocessor cards;

— the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it in accordance with this part of ISO 21549).

The following topics are therefore beyond the scope of this part of ISO 21549:

— physical or logical solutions for the practical functioning of particular types of data card;

— how the message is processed further “downstream” of the interface between two systems;

— the form which data take for use outside the data card, or the way in which such data are visibly represented on the data card or elsewhere.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 7498-2:1989, *Information processing systems — Open systems interconnection — Basis reference model — Part 2: Security architecture*

ISO/IEC 7810, *Identification cards — Physical characteristics*

ISO 21549-2:2004, *Health informatics — Patient healthcard data — Part 2: Common objects*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
confidentiality
the property that information is not made available or disclosed to unauthorized individuals, entities or processes

[ISO 7498-2:1989]

3.2
data integrity
the property that data have not been altered or destroyed in an unauthorized manner

[ISO 7498-2:1989]

3.3
data object
collection of data that has a natural grouping and may be identified as a complete entity

3.4
data origin authentication
corroboration that the source of data received is as claimed

[ISO 7498-2:1989]

3.5
healthcard holder
individual transporting a healthcare data card which contains a record with the individual identified as the major record person

3.6
healthcare data card
machine-readable card, conformant to ISO 7810, intended for use within the healthcare domain

3.7
linkage
ability to join together two or more entities or parts

NOTE It may be physical, electrical or relational.

3.8
record
collection of data

3.9
record person
individual about whom there is an identifiable record containing person-related data

3.10
security
combination of confidentiality, integrity and availability

4 Symbols and abbreviated terms

ASN.1 Abstract syntax notation, version 1

EN European Standard

HCP Healthcare person

IEC International Electrotechnical Commission

ISO International Organization for Standardization

UML Unified modelling language

UTC Coordinated universal time

5 Basic data object model for a healthcare data card — Patient healthcard data object structure

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

The tools consist of a generic data structure based on an object-oriented model represented as a UML class diagram as shown below in Figure 1.

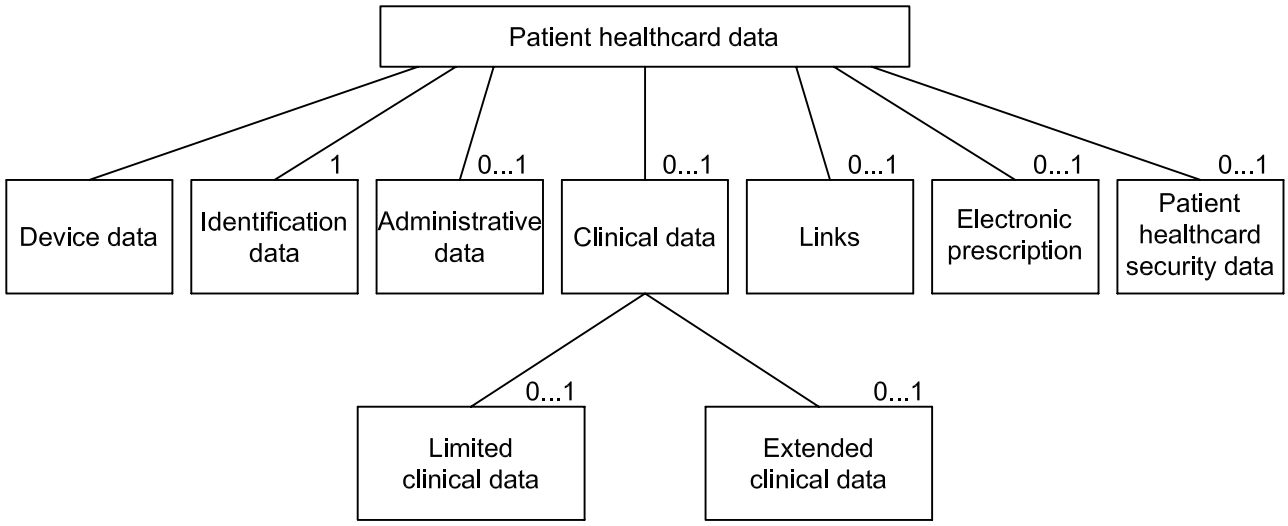

Figure 1 — Patient healthcard data — Overall structure

The content of this object-oriented structure is described below and intrinsically will also require the use of data objects not defined within this part of ISO 21549.

NOTE 1 This part of ISO 21549 is solely applicable to patient healthcards containing health data. Data objects containing financial and healthcare reimbursement data are not defined in this International Standard.

NOTE 2 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, this International Standard allows 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.

6 Basic data objects for referencing

6.1 Overview

A series of generally useful data type definitions have been made that have no intrinsic value in themselves, but which are used to define other objects in this multi-part standard. Operations may be performed with these objects in association with other information objects to “add value”. These objects have been given formal definitions in ISO 21549-2.

6.2 Coded data

Coded values are understood by reference to the coding scheme to which they apply. The general principle in this part of ISO 21549 is that it is not mandatory to use a particular coding scheme, unless specified in this part of ISO 21549, when such codes act as parameters. One example is the use of ISO 3166-1 for country codes.

When a coding scheme is exclusively specified in this part of ISO 21549, no alternative coding scheme shall be allowed. Any references to coding schemes not so specified may, however, be modified in the future, independently of the rest of the standard.

The data object “CodedData” shall be constructed in accordance with the definition contained in ISO 21549-2.

6.3 Device and data security attributes

Data stored in data cards used in healthcare may be personally sensitive. For this reason, this part of ISO 21549 utilizes a series of security attributes, defined in ISO 21549-2. The actual data content (value) is not within the scope of this part of ISO 21549, nor are the mechanisms that make use of these data elements. It is emphasized that the security attributes cannot satisfy given security requirements without the implementation of the appropriate security functions and mechanisms in the data card.

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 healthcare 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. This 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 data card. 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 a data card such as on re-generation after failure.

6.4 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 as defined in ISO 21549-2.

7 Limited clinical data

7.1 General

The limited clinical data object is specifically divided into three separate data sets: a limited emergency data set, a blood grouping and transfusion record data set and an immunizations received data set. Because of their groupings, each of these can have differing security settings, including access rights as determined by the provisions contained within accessory attributes.

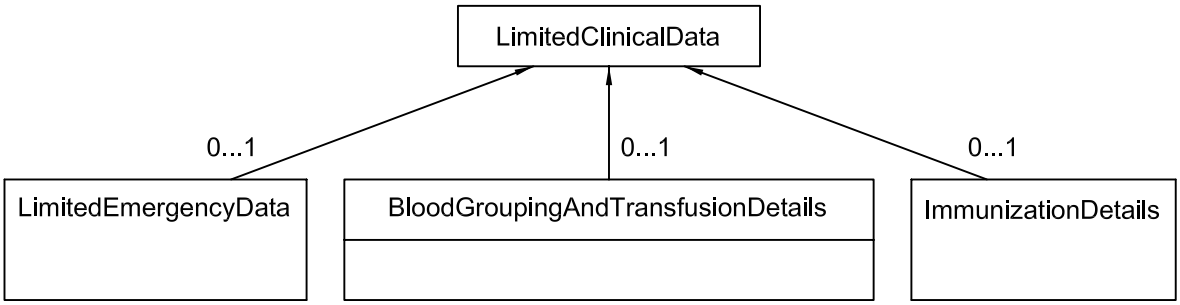

Figure 2 — Structure of the “LimitedClinicalData” data set

Table 1 — The specification of individual entities within the patient data set

	Data type	Multiplicity	Comments
ImmunizationDetails	Class	0...1	This class holds the immunization records in relation to the record person.
LimitedEmergencyData	Class	0...1	This class holds the emergency medical record of the record person.
BloodGroupingAndTransfusion Details	Class	0...1	This class holds the blood group and records appertaining to any blood products received by the record person.

7.2 The limited emergency data set

The object “LimitedEmergencyData” shall consist of a set of data consisting of “EmergencyDataBitMap”, a sequence of booleans within which the status “true” shall indicate the presence of the condition in the record person or, in the case of a medication, that the record person *may* be taking this medication, plus the optional element “AccessoryAttributes”. This object is intended to convey the majority of the fixed clinical data set defined within the draft International emergency health record in addition to data normally communicated by patient-carried warning cards and “MedicAlert” tokens.

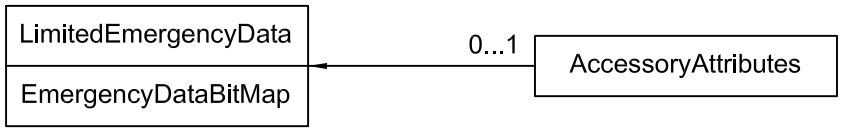

Figure 3 — Structure of “LimitedEmergencyData” data set

Table 2 — The specification of individual entities within "LimitedEmergencyData" data set

Attribute Name	Data type	Multiplicity	Length	Comments
EmergencyDataBitMap	Booleans	1	5	Sequence of Booleans.
AccessoryAttributes	Class	0...1		A class that incorporates data that determine authentication and authorization in particular.

7.3 Immunization details

The immunization record contained within ImmunizationDetails is intended to provide a record of immunizations received by the record person and is deliberately separate from other coded clinical data in order that it can be attributed differing security status. It is normal practice that this type of information would be accorded the same level of security status as the LimitedEmergencyData.

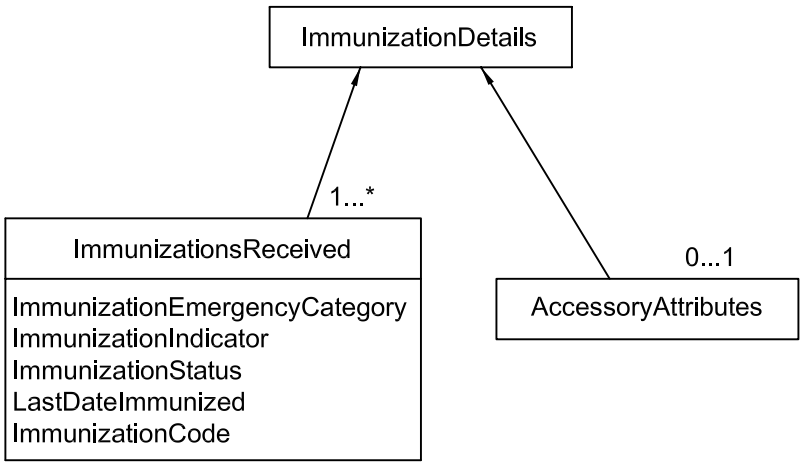

Figure 4 — Structure of "ImmunizationDetails"

Table 3 — The specification of individual entities within "ImmunizationDetails"

Attribute name	Data type	Multiplicity	Length	Comments
ImmunizationsReceived	Class	1		
ImmunizationIndicator	Enumerated	1	1	Never(0), one or more(1), unknown(2), adverse reaction(4).
ImmunizationStatus	Enumerated	1	1	Unspecified(0), first dose(1), second dose(2), third dose(3), completed course(4), booster(5).
LastDateImmunized	Date	0...1		
ImmunizationCode	Coded data	1		The actual coded data meaning of the immunization.
AccessoryAttributes	Class	0...1		A class that incorporates data that determines authentication and authorization in particular.

7.4 Blood grouping and transfusion record

The blood grouping and transfusion record is intended to be a separate data object from the rest of the patient data set in order that it can be attributed differing security privileges in the same fashion as the emergency and immunization record. It is intended to record, where known, the record person's blood group and carry data regarding any blood products the person may have received.

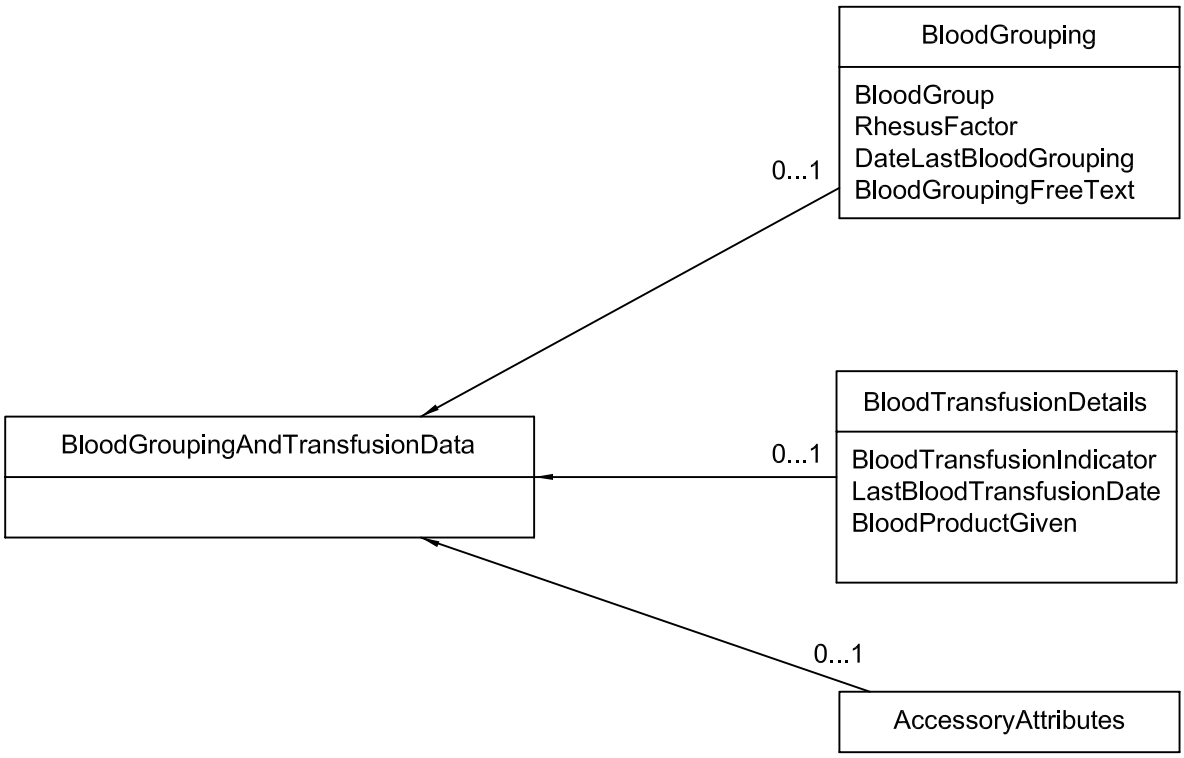

Figure 5 — Structure of "BloodGroupingAndTransfusionData"

Table 4 — The specification of individual entities within "BloodGroupingAndTransfusionData"

Attribute name	Data type	Multiplicity	Length	Comments
BloodGrouping	Class	0...1		Holds data on the blood group of the record person.
BloodGroup	String	1	2	Contains data recording the blood group.
RhesusFactor	String	1	1	Contains data recording the rhesus factor.
DateLastBloodGrouping	Date	0...1	8	Contains the date of the last blood grouping.
BloodGroupingFreeText	String	0...1	30	Allows free text entry describing the blood grouping.
TransfusionData	Class	0...1		Holds data on blood products received by the record person.
LastBloodTransfusionDate	Date	0...1	8	Contains the recorded date of the last blood transfusion.
BloodProductGiven	Coded data	1		Records the type of blood product given using the structure of CodedData.
AccessoryAttributes	Class	0...1		A class that incorporates data that determines authentication and authorization in particular.

Annex A
(normative)

ASN.1 data definitions

A.1 "LimitedEmergencyData"

```
LimitedEmergencyData        ::=  SET
{EmergencyDataBitMap        ::=  [0] SEQUENCE OF BOOLEANS
{
Asthma                                  [0],
HeartDisease                            [1],
CardiovascularDisease                   [2],
EpilepsyFits                            [3],
NeurologicalDisorder                    [4],
CoagulationDisorder                     [5],
Diabetes                                [6],
Glaucoma                                [7],
DialysisTreatment                       [8],
TransplantedOrgan                       [9],
MissingOrgan                            [10],
RemovableProsthesis                     [11],
PacemakerInSitu                         [12],
SlowAcetylator                          [13],
TakingAntipsychoticMedication           [14],
TakingAnticonvulsants                   [15],
TakingAntiarrythmics                    [16],
TakingBloodPressureDrugs                [17],
TakingAnticoagulants                    [18],
TakingAntidiabeticAgents                [19],
TakingAntihistamines                    [20],
ReceivedStreptokinase                   [21],
AllergicToAnalgesics                    [22],
AllergicToAnimalHair                    [23],
AllergicToAntibiotics                   [24],
AllergicToCitrusFruits                  [25],
AllergicToHouseDust                     [26],
AllergicToEggs                          [27],
AllergicToFish/Shellfish                [28],
AllergicToIodine                        [29],
AllergicToMilk                          [30],
AllergicToNuts                          [31],
AllergicToPollens                       [32],
AllergicToOtherAgent                    [33],
OtherData                               [34]
                                            -- Boolean set to true indicates that more information is
                                            -- contained within extended clinical data.
}
AccessoryAttributes             [1] OPTIONAL
}
```

A.2 “ImmunizationDetails”

```
ImmunizationDetails              ::=  SET
{ImmunizationsReceived           [0] SET OF Immunization
Immunization                     ::=  SET
{ImmunizationEmergencyCategory       [0]
ImmunizationIndicator                [1] ENUMERATED
                                       --  Never(0), one or more(1), unknown(2), adverse
                                       reaction(4)
ImmunizationStatus                   [2] ENUMERATED
                                       --  Unspecified(0), first dose(1), second dose(2), third
                                       dose(3), completed course(4), booster(5)
LastDateImmunized                    [3] Date OPTIONAL,
ImmunizationCode                     [4] CodedData,
}
AccessoryAttributes              [1] OPTIONAL
}
```

A.3 “BloodGroupingAndTransfusionData”

```
BloodGroupingAndTransfusionData  ::=  SET
{BloodGrouping                   [0],
{BloodGroup                          [0] ENUMERATED,
                                       --  “O” = 0, “A” = 1, “B” = 2, “AB” = 3
RhesusFactor                         [1] ENUMERATED
                                       --  “0” = +ve, “1” = –ve
DateLastBloodGrouping                [2] UTC time,
BloodGroupingFreeText                [3] OCTET STRING (SIZE(1-30))
}
{BloodTransfusionData            [1],
   {BloodTransfusionIndicator        [0] ENUMERATED,
                                       --  0 = Never, 1 = Once, 2 = More than once
   LastBloodTransfusionDate          [1] UTC Time,
   BloodProductGiven                 [2] CodedData
   }
AccessoryAttributes              [2] OPTIONAL
}
```

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