INTERNATIONAL STANDARD

ISO 20301

Second edition 2014-01-15

Health informatics — Health cards — General characteristics

Informatique de santé — Cartes de santé — Caractéristiques générales



ISO 20301:2014(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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 20301:2006), of which it constitutes a minor revision.

Introduction

The purpose of using machine-readable cards in the field of healthcare is to improve the quality of health service and the efficient use of healthcare resources in the field. The primary consideration in creating this International Standard has been to improve patient service and patient safety, as well as improve the practical use of healthcare cards in clinical fields.

Standardizing the clinical practice of medicine and defining a standardized healthcare delivery service structure are not included in this International Standard.

In years past, healthcare cards have been used to exchange healthcare data by placing necessary and appropriate information on the surface of the cards in order to implement the health service of each country. However, as people now move more frequently across borders, healthcare cards issued in one country or area are increasingly being used in another, and with this consideration in mind, this International Standard has been designed to apply to healthcare cards that will be used internationally.

It would be pertinent for ISO/TC 215 and ISO/IEC JTC1/SC 17 to discuss the standardization of the characteristics and operation of other cards, which are not covered by this International Standard.

This International Standard is designed to accept relevant technologies and recording techniques for cards.

The data elements and data structures in healthcare cards are under consideration within ISO/TC 215.

Health informatics — Health cards — General characteristics

1 Scope

This International Standard describes general characteristics of machine-readable cards used in the field of healthcare.

This International Standard is designed to confirm the identities of both the healthcare application provider and the healthcare cardholder in order that information can be exchanged by using cards issued for healthcare service.

This International Standard focuses on the machine-readable cards of ID-1 type defined in ISO/IEC 7810 that are issued for healthcare services provided in a service area that crosses the national borders of two or more countries/areas.

This International Standard applies directly or refers to existing ISO standards for the physical characteristics and recording techniques. Security issues follow the requirements of each healthcare card system.

In addition, this International Standard regulates the visual information written on the card.

2 Normative references

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

ISO 21549-1:2013, Health informatics — Patient healthcard data — Part 1: General structure

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

ISO/IEC 7810, Identification cards — Physical characteristics

ISO/IEC 7811 (all parts), *Identification cards* — *Recording technique*

ISO/IEC 7812-1, Identification cards — Identification of issuers — Part 1: Numbering system

ISO/IEC 7816 (all parts), Identification cards — Integrated circuit cards

ISO/IEC 10373 (all parts), *Identification cards* — *Test methods*

ISO/IEC 10536 (all parts), *Identification cards* — *Contactless integrated circuit(s) cards* — *Close-coupled cards*

ISO/IEC 11693 (all parts), Identification cards — Optical memory cards

ISO/IEC 14443 (all parts), Identification cards — Contactless integrated circuit cards — Proximity cards

ISO/IEC 15420 (all parts), Information technology — Automatic identification and data capture techniques — EAN/UPC bar code symbology specification

ISO/IEC 15438 (all parts), Information technology — Automatic identification and data capture techniques — PDF417 bar code symbology specification

ISO/IEC 15693 (all parts), *Identification cards* — *Contactless integrated circuit cards* — *Vicinity cards*

ISO/IEC 24789 (all parts), *Identification cards* — *Card service life*

3 Terms and definitions

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

3.1

application

provided for specific services in healthcare fields, which could be carried out by using a separate set of information stored in the healthcare data card

EXAMPLE An application for making appointments for medical treatment, an application for providing access to medical records, and an application for certifying health funding status are all examples of healthcare applications.

3.2

card issuer

entity that records the information to activate the card, register, and distribute to the healthcare cardholder

EXAMPLE A hospital could be an issuer of cards for handling appointments for medical treatment or for accessing medical records. A health funding agency could be an issuer of cards for health funding.

3.3

field identifier

character strings, numeric characters, and/or icons placed near the visually readable data that help to identify the data

3.4

front side of the card back side of the card

front/back side of the card is defined in standards related to the applied recording techniques and card technologies, e.g. ISO/IEC 7811 for cards with embossing and/or magnetic stripes, ISO/IEC 7816 for integrated circuit cards, and ISO/IEC 11693 (all parts) for optical memory cards

3.5

healthcare application provider

entity that provides healthcare services to the healthcare cardholder and in the course of doing so, makes use of the card and records the health care application information onto the cards

EXAMPLE A hospital could be a healthcare application provider by handling appointments for medical treatment or by providing access control to medical records. A health funding agency could be a healthcare application provider by issuing cards for health funding. A health funding agency could also be a healthcare application provider by certifying the health funding status of the healthcare cardholder.

Note 1 to entry: If the card contains an application for medical appointments, a hospital could be an application provider as it provides appointment services to the patients, while it could also be a user of the card if the card contains an application for health funding services, as the hospital could get reimbursed from the health funding agency.

3.6

healthcare data card

card conformant to ISO/IEC 7816 (all parts) intended for use within the healthcare domain

[SOURCE: ISO 21549-1:2013, definition 3.2]

3.7

healthcare cardholder

individual transporting a healthcare data card, which contains a record with the individual identified as the major record person

[SOURCE: ISO 21549-2:2004, definition 3.8]

3.8

item

single distinct part of the visually readable data

3.9

recording technique

technique to put visually readable data onto the card surface or to write data in non-volatile memories

3.10

service area

countries/areas where the healthcare data card is intended to be used and where the healthcare service obtained by using the card is provided

3.11

visually readable data

data that are placed on the surface of the healthcare data card to be read visually by users

4 Abbreviated terms

PAN Primary Account Number

IIN Issuer Identification Number

5 Physical characteristics

The physical characteristics follow the specifications defined by ISO/IEC 7810 and the specifications defined by the International Standards for the recording techniques. For example, ISO/IEC 7811 for cards using embossing and/or magnetic stripes, ISO/IEC 7816 for cards using IC with contacts, and ISO/IEC 11693 (all parts) for optical memory cards.

The physical characteristics of a healthcare card shall be in compliance with the relevant standards of the applied recording techniques and card technologies, for example, ISO/IEC 7811 for cards with embossing and/or magnetic stripes, ISO/IEC 7816 for integrated circuit cards, ISO/IEC 14443, ISO 10536, and ISO 15693 for contactless integrated circuit cards, and ISO/IEC 11693 (all parts) for optical memory cards.

6 Visually readable data

6.1 Purposes of visually readable data

The items defined by this International Standard are designed for either of the following two purposes.

Purpose 1: Identification of the application provider and healthcare cardholder.

Purpose 2: Provision of information for contacting the card issuer and the healthcare cardholder within the service area.

The visually readable data may not be meant to replace or may not be the same as the data stored within the card by means of magnetic, optical memory, electronic, or other machine-readable technologies. Also, other visually readable information or items can appear on the card.

6.2 Items of visually readable data

6.2.1 Application provider identifier

The application provider identifier shall follow the regulations below for purpose 1 defined in 6.1.

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The written or drawn information to identify the application provider shall appear on the card.

The identifier shall be written or drawn in one or more languages that could be understood within the service area.

This item shall be written or drawn on the same side as the healthcare cardholder identifier.

The application provider identifier can follow:

- the PAN defined in ISO/IEC 7812-1 when the application provider identifier is combined with the cardholder identifier defined in 6.2.2;
- ISO 20302.

6.2.2 Healthcare cardholder identifier

The healthcare cardholder identifier shall appear on the card, and follow the regulations below for purpose 1 defined in 6.1.

The name or the information of the healthcare cardholder defined by the healthcare application provider shall appear on the card.

The healthcare cardholder identifier shall be written or drawn in one or more languages that could be understood within the service area.

This item shall be written or drawn on the same side as the application provider identifier.

The healthcare cardholder identifier can follow the PAN for the cardholder identifier defined in ISO/IEC 7812-1 when it is combined with the application provider identifier defined in <u>6.2.1</u>.

6.2.3 Application name

Application name can follow the regulations below for purpose 1 defined in 6.1.

The application name can appear on the healthcare data card as the title of the healthcare service provided by the application provider.

The application name can be written or drawn in one or more languages that could be understood within the service area.

The application name can

- a) be followed by a field identifier in one or more languages that could be understood within the service area, and
- b) appear on either side of the card on top or in the largest font.

6.2.4 Information for contacting the card issuer

The information for contacting the card issuer shall appear on the card. Information for contacting the card issuer can follow the regulations below for purpose 2 defined in <u>6.1</u>.

The written or drawn information to contact the card issuer shall appear on the card.

Information for contacting the card issuer shall be written or drawn in one or more languages that could be understood within the service area.

6.2.5 Country/area of the card issuer

The country/area of the card issuer can follow the regulations below for purpose 2 defined in 6.1.

The written or drawn information to identify the country/area of the card issuer can appear on the card.

This item can be removed if any other visually readable data contain the information for identifying the country/area of the card issuer.

The country/area of the card issuer can follow ISO 3166, while it allows other forms such as code, character, letter, icon, and other information that is understood within the service area.

EXAMPLE Following ISO 3166, the country of the card issuer can be addressed by a code based on two or three letters of the alphabet such as 'JP' or 'JPN' for Japan or numeric numbers such as '392' for Japan.

6.2.6 Other information

The card can include additional information not covered above, such as a photograph and/or signature panel.

6.3 Field identifier of visually readable data

If the visually readable data on the card is not readily discernable in the service area, field identifiers can be added.

Examples of field identifiers written in Latin-1 code are shown in Annex A.

7 Recording technique

7.1 Recording technique for visually readable data

7.1.1 Writing, printing, engraving, drawing, and lasering

To put visually readable data on the card surface, recording techniques such as writing, printing, engraving, drawing, and lasering can be used.

7.1.2 Embossing

Embossing can be used to put visually readable data on the card surface. When using embossing, the location, documentation procedure, and character type shall follow ISO/IEC 7811-1.

7.2 Magnetic stripes

Magnetic stripes can be used to put visually readable data on the card surface. When using magnetic stripes, the location and the documentation procedure shall follow ISO/IEC 7811-2 and ISO/IEC 7811-6.

7.3 Integrated circuits with contacts

ICs with contacts can be used to put visually readable data on the card surface. When using ICs with contacts, the location of contacts shall follow ISO/IEC 7816.

7.4 Contactless integrated circuits

Contactless ICs can be used to put visually readable data on the card surface. When using cards with contactless ICs, the contactless interface shall follow ISO/IEC 10536, ISO/IEC 14443, and/or ISO/IEC 15693.

7.5 Optical memory

Optical memory can be used to put visually readable data on the card surface. When using an optical memory, the location of the memory shall follow ISO/IEC 11693 (all parts).

7.6 Other recording technique

Recording techniques other than those described above can be used on the healthcare data card for machine-readable purposes. For example, one-dimensional or two-dimensional bar codes can be used by following ISO/IEC 15420 or ISO/IEC 15438. When using more than two recording techniques, and if discrepancies occur, the healthcare provider should resolve the problem before issuing the healthcare data card.

8 Test method

Test methods for healthcare cards should follow ISO/IEC 10373 and ISO/IEC 24789.

Annex A

(informative)

Examples of field identifiers written in Latin-1 code

- Use "<title>" for "Application name".
- Use "rovider>" for "Application provider identifier".

This field identifier can be used if the identifier is an identification code such as an ID number or a character string such as a name.

- Use "<provider ID>" for "Application provider identifier" if the identifier is an identification code such as an ID code.
- Use "<provider Name>" for "Application provider identifier" if the identifier is a character string such as a name.
- Use "<holder>" for "Healthcare cardholder identifier".

This field identifier can be used where the identifier is an identification code such as an ID number or a character string such as a name.

- Use "<holder ID>" for "Healthcare cardholder identifier" if the identifier is an identification code such as an ID number.
- Use "<holder Name>" for "Healthcare cardholder identifier" if the identifier is a character string such as a name.
- Use "<address>" for "Information for contacting card issuer".

Annex B

(informative)

Examples of healthcare card layout

B.1 General

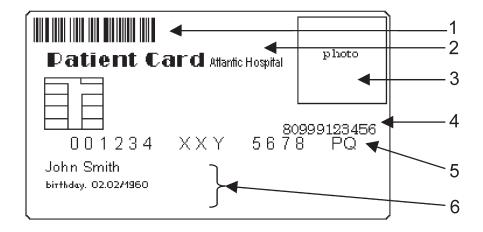
This annex shows an example of the healthcare data card layout regulated by this International Standard. With this International Standard, the size and placement of each data item is not regulated.

B.2 Examples of layout

B.2.1 Example layout 1: Both side layout

Figure B.1 shows the healthcare data card layout of the front side without field identifiers regulated by this International Standard and Figure B.2 shows the reverse side.

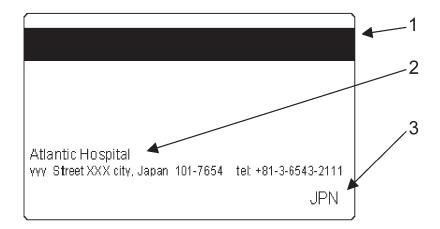
These examples are conceptual and so are not drawn to scale.



Key

- 1 bar code
- 2 application name
- 3 photograph
- 4 identifier of the healthcare application provider
- 5 identifier of the healthcare cardholder
- 6 additional information

Figure B.1 — Example of the front-side layout



Key

- 1 magnetic stripe
- 2 information for contacting the card issuer
- 3 registration country of the card issuer

Figure B.2 — Example of the back-side layout

IIN defined by ISO/IEC 7812-1 is used for the identifier of the healthcare service provider. It contains '80' as the healthcare sector, '999' as the country code, '12345' as the issuer number, and '6' as the checksum digit.

15 letters including letters and numbers are used as the healthcare cardholder identifier.

The address and telephone number of the card issuer are documented on the back side of the card as the contact information.

The country/area of the card issuer is documented on the back side of the card.

The contacts of the IC are located on the upper left of the front side of the card, following ISO/IEC 7816.

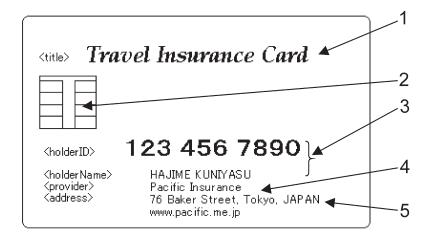
A bar code appears on the upper left of the front side of the card.

A photograph of the healthcare cardholder appears on the upper right of the front side of the card.

The magnetic stripe is located on the upper part of the back side of the card, following ISO/IEC 7811.

B.2.2 Example layout 2: Single side layout

Figure B.3 shows an example of the front side healthcare data card layout using field identifiers.



Key

- 1 application name
- 2 contacts of IC
- 3 healthcare cardholder identifiers
- 4 identifier of the application provider
- 5 information for contacting the card issuer

Figure B.3 — Example of the front layout

This example is conceptual so is not drawn to scale.

All items are combined with field identifiers.

Two types of healthcare cardholder identifiers are denoted. One is the ID number and the other is the name.

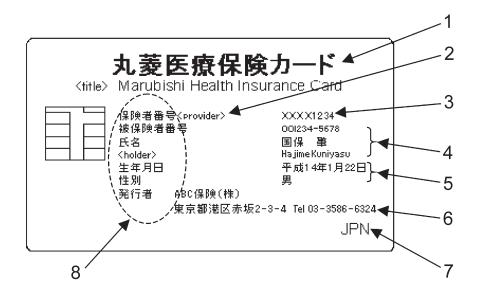
The country/area of the card issuer is eliminated because the issuing country can be recognized from the information for contacting the card issuer.

In this example, contacts for the IC are located on the upper left of the front of the healthcare data card, in accordance with ISO/IEC 7816.

B.2.3 Example layout 3: Non-alphabetical character layout

Figure B.4 shows an example of the front layout regulated by this International Standard, which uses the non-Latin-1 code characters understandable throughout the cross-border service area.

This example is conceptual and so is not drawn to scale.



Key

- 1 application name
- 2 field identifier for identifier of the healthcare application provider
- 3 identifier of the healthcare application provider
- 4 healthcare cardholder identifiers
- 5 additional information
- 6 information for contacting the card issuer
- 7 county/area of the card issuer
- 8 non-Latin-1 field identifiers for each item

Figure B.4 — Example of the front-side layout

The application name is written in two languages. The field identifier in English follows the examples described in Annex A.

The identifier of the healthcare application provider is printed as an ID number and the field identifier in English follows the examples described in Annex A.

The healthcare cardholder identifier is printed as a card number provided by the healthcare application provider.

The healthcare cardholder's name is printed in English and the same name is printed with non-Latin-1 code characters. Date of birth and sex are printed as additional information.

Field identifiers printed in non-Latin-1 code accompany the identifier of the healthcare application provider, the healthcare cardholder identifier, and the additional information, but no field identifier accompanies the information for contacting the healthcare cardholder because the address and the telephone number are clearly understood in the service area.

IC contacts are located in accordance with ISO/IEC 7816 on the upper-left side of the front of the healthcare data card. However, this is not mandatory.

Bibliography

- [1] ISO 3166, Codes for the representation of names of countries
- [2] ISO 20302, Health informatics Health cards Numbering system and registration procedure for issuer identifiers
- [3] ISO/IEC 11694 (all parts), Identification cards Optical memory cards Linear recording method

