

INTERNATIONAL STANDARD

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Health informatics — Health cards — General characteristics

Informatique de santé — Cartes de santé — Caractéristiques générales

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Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 Abbreviations	3
5 Physical characteristics	3
6 Visually readable data	3
6.1 Purposes of visually readable data.....	3
6.2 Items of visually readable data.....	4
6.3 Field identifier of visually readable data (optional).....	5
7 Recording technique	5
7.1 Recording technique for visually readable data.....	5
7.2 Magnetic stripe.....	5
7.3 Integrated circuits with contacts.....	5
7.4 Contactless integrated circuits	6
7.5 Optical memory.....	6
7.6 Other recording technique.....	6
8 Test method.....	6
Annex A (informative) Examples of field identifiers written in Latin-1 code.....	7
Annex B (informative) Examples of healthcare data card layout	8
Bibliography	12

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 20301 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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Introduction

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

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 data cards in clinical fields.

The main policy of this International Standard is as follows.

- 1) ISO/TC215 has agreed to exempt the following items from standardization efforts:
 - standardizing the clinical practice of medicine and
 - defining a standardized healthcare delivery service structure.

In past years, healthcare data 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 data 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 data cards that will be used internationally.

- 2) This International Standard is applicable to healthcare data cards used for healthcare services provided by the card issuer. Not only ISO/TC 215, but also ISO/IEC JTC1/SC17 should discuss the standardization of the characteristics and operation of other cards, which are not covered by this International Standard.
- 3) This International Standard is designed to accept relevant technologies and recording techniques for healthcare data cards.

The data elements and data structures in healthcare data cards are under consideration within ISO/TC215/WG 5.

Health informatics — Health cards — General characteristics

1 Scope

This International Standard is designed to confirm the identities of both the healthcare application provider and the healthcard holder in order that information may 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 to healthcare data cards where the issuer and the application provider are the same party.

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

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

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 (all parts), *Codes for the representation of names of countries and their subdivisions*

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 (with contacts)*

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, *Identification cards — Optical memory cards — General characteristics*

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

ISO/IEC 15420, *Information technology — Automatic identification and data capture techniques — Bar code symbology specification — EAN/UPC*

ISO/IEC 15438, *Information technology — Automatic identification and data capture techniques — PDF417 bar code symbology specification*

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

ISO 20302, *Health informatics — Health cards — Numbering system and registration procedure for issuer identifiers*

3 Terms and definitions

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

3.1 application

that which is provided for specific services in healthcare fields and 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 healthcard holder

EXAMPLE A hospital could be a card issuer of cards for handling appointments for medical treatment or for accessing medical records. A health funding agency could be a card 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 visually readable data

3.4 front side of the card back side of the card

see International Standards related to the applied recording techniques and card technologies, namely:

- ISO/IEC 7811 for cards with embossing and/or magnetic stripe;
- ISO/IEC 7816 for integrated circuit cards;
- ISO/IEC 14443 for contactless integrated circuit cards (proximity cards);
- ISO/IEC 11693 for optical memory cards

3.5 healthcare application provider

entity that provides healthcare services to the healthcard holder and in the course 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 healthcard holder.

NOTE 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 may get reimbursed from the health funding agency.

3.6 healthcare data card

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

[ISO 21549-1:2004, definition 3.2]

3.7**healthcard holder**

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

[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 Abbreviations

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 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 for optical memory cards.

The physical characteristics of a healthcare data card shall be in compliance with the relevant standards of the applied recording techniques and card technologies, e.g. ISO/IEC 7811 for cards with embossing and/or magnetic stripe, ISO/IEC 7816 for Integrated circuit cards, ISO/IEC 14443, ISO 10536, and ISO 15693 for contactless integrated circuit cards, and ISO/IEC 11693 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 two purposes below.

Purpose 1): Identification of the application provider and healthcard holder.

Purpose 2): Provision of information for contacting the card issuer and the healthcard holder 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 may appear on the card.

6.2 Items of visually readable data

6.2.1 Application provider identifier (mandatory)

The application provider identifier shall follow the regulations below, for Purpose 1) defined in 6.1.

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 healthcard holder identifier.

The application provider identifier may follow:

- 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 Healthcard holder identifier (mandatory)

The healthcard holder identifier shall follow the regulations below, for Purpose 1) defined in 6.1.

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

The healthcard holder 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 healthcard holder identifier may follow PAN for cardholder identifier defined in ISO/IEC 7812-1 when it is combined with the application provider identifier defined in 6.2.1.

6.2.3 Application name (optional)

Application name may follow the regulations below, for Purpose 1) defined in 6.1.

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

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

The application name may:

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

6.2.4 Information for contacting the card issuer (mandatory)

Information for contacting the card issuer may follow the regulations below, for Purpose 2) defined in 6.1.

The written or drawn information to contact the card issuer shall appear on the healthcare data 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 (optional)

The country/area of the card issuer may 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 may appear on the healthcare data card.

This item may 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 may 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 may be addressed by a code based on 2 or 3 letters of the alphabet such as 'JP' or 'JPN' for Japan, or numeric numbers such as '392' for Japan.

6.2.6 Other information (optional)

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

6.3 Field identifier of visually readable data (optional)

If the visually readable data on the healthcare data card are not readily discernable in the service area, field identifiers may 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, lasering

For putting visually readable data on the card surface, recording techniques such as writing, printing, engraving, drawing and lasering may be used.

7.1.2 Embossing

Embossing may be used for putting 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 stripe

Magnetic stripe may be used for putting visually readable data on the card surface. When using magnetic stripe, the location and the documentation procedure shall follow ISO/IEC 7811 Part 2 and Part 6.

7.3 Integrated circuits with contacts

IC chip with contacts may be used for putting visually readable data on the card surface. When using IC with contacts, the location of contacts shall follow ISO/IEC 7816.

7.4 Contactless integrated circuits

Contactless IC chip may be used for putting visually readable data on the card surface. When using healthcare data cards with contactless IC, the location of contactless IC shall follow ISO/IEC 10536, ISO/IEC 14443 and/or ISO/IEC 15693.

7.5 Optical memory

Optical memory may be used for putting visually readable data on the card surface. When using an optical memory, the location of the memory shall follow ISO/IEC 11693.

7.6 Other recording technique

Recording techniques other than those described above may be used on the healthcare data card for machine-readable purposes. For example, one-dimensional or two-dimensional bar codes may 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 data cards should follow ISO/IEC 10373.

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Annex A (informative)

Examples of field identifiers written in Latin-1 code

— Use “<title>” for “Application name”.

— Use “<provider>” for “Application provider identifier”.

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

— Use “<provider ID>” for “Application provider identifier” if the identifier is an identification code such as ID code.

— Use “<provider Name>” for “Application provider identifier” if the identifier is a character string such as name.

— Use “<holder>” for “Healthcard holder identifier”.

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

— Use “<holder ID>” for “Healthcard holder identifier” if the identifier is an identification code such as ID number.

— Use “<holder Name>” for “Healthcard holder identifier” if the identifier is a character string such as name.

— Use “<address>” for “Information for contacting card issuer”.

Annex B (informative)

Examples of healthcare data card layout

B.1 General

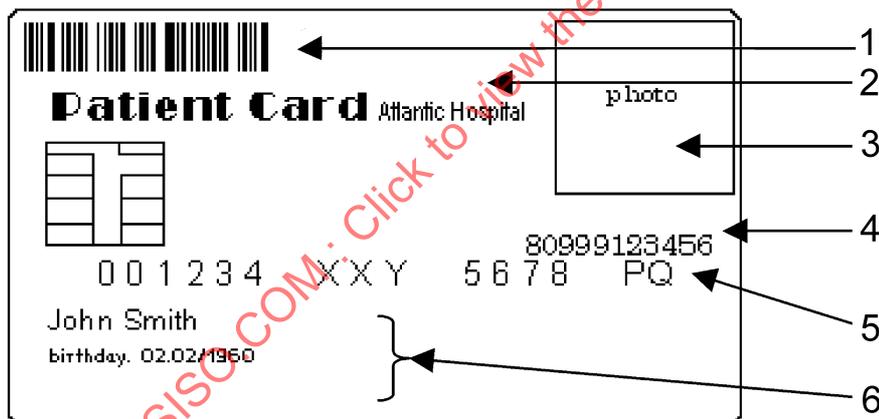
This Annex shows an example of the healthcare data card layout regulated by this International Standard. With this International Standard, the size and placement of each data item is not regulated.

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.

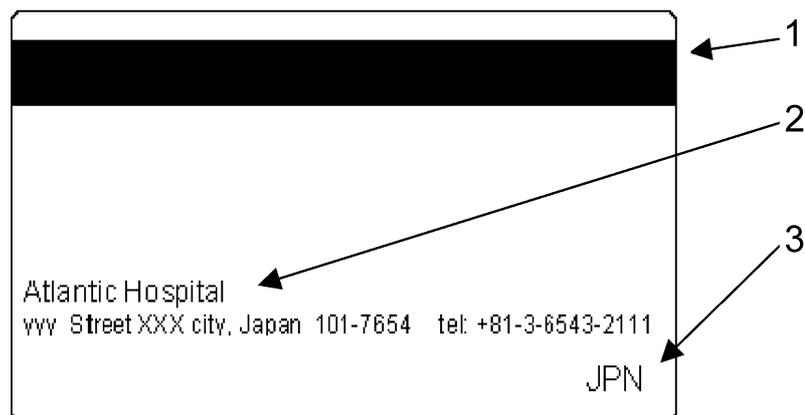
These examples are conceptual and so are not drawn to scale.



Key

- | | |
|-------------------------------|---|
| 1 bar code (optional) | 4 identifier of the healthcare application provider (mandatory) |
| 2 application name (optional) | 5 identifier of the healthcard holder (mandatory) |
| 3 photograph (optional) | 6 additional information (optional) |

Figure B.1 — Example of the front side layout (1)



Key

- 1 magnetic stripe (optional)
- 2 information for contacting with the card issuer (mandatory)
- 3 registration country of the card issuer (optional)

Figure B.2 — Example of the back side layout (1)

Mandatory data:

- IIN defined by ISO/IEC 7812-1 is used for the Identifier of the healthcare service provider defined as mandatory data. It contains '80' showing healthcare sector, '999' as the country code, '12345' as issuer number and '6' as the checksum digit.
- 15 letters including alphabet and numbers are used as the healthcard holder identifier.
- The address and telephone number of the card issuer are documented on the back side of the healthcare data card as the contact information.

Non-mandatory data:

- The country/area of the card issuer is documented on the back side of the healthcare data card.
- The contacts of IC are located in the upper left on the front side of the healthcare data card, in accordance with ISO/IEC 7816.
- A bar code appears in the left upper on the front side of the healthcare data card.
- A photograph of the healthcard holder appears in the upper right on the front side of the healthcare data card.
- The magnetic stripe is located in the upper part of the back side of the healthcare data card, in accordance with 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 regulated by this International Standard using field identifiers.



Key

- 1 application name (optional)
- 2 contacts of IC chip (optional)
- 3 healthcard holder identifiers (mandatory)
- 4 identifier of the application provider (mandatory)
- 5 information for contacting the card issuer (mandatory)

Figure B.3 — Example of the front layout (2)

This example is conceptual so is not drawn to scale.

All items are combined with field identifiers.

Two types of healthcard holder identifier 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 chip are located in the upper left on 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.