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Health informatics — Medical waveform format —

Part 1: **Encoding rules**

Informatique de santé — Format de la forme d'onde médicale —

Partie 1: Règles d'encodage

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Foreword

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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).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 22077-1:2015) of which it constitutes a minor revision. The changes are as follows:

— some typographical errors have been corrected;

— Clause 2 “Normative references” has been added;

— Note 1 to entry has been added to terminology entries 3.1.1, 3.1.3 and 3.1.4, and terminology entry 3.1.5 has been added;

— classifications and types of waveform in Table 10 have been added;

— the character code in Table 39 has been changed;

— a Bibliography has been added.

A list of all parts in the ISO 22077 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Medical waveform data such as an electrocardiogram (ECG) or an electroencephalogram (EEG) are widely utilized in physiological examinations, physiological research, electronic medical records, healthcare information and other areas in the clinical field. Medical waveform data can be used for many medical and research purposes if digital signal processing technology is applied to standardize the data in a digital format. For medical waveforms, it is essential to standardize the data format to expedite the mutual application of the standard so that the data can be processed electronically and used in a variety of ways.

Simple and easy implementation: the application of medical waveform format encoding rules (MFER) is very simple and is designed to facilitate understanding, easy installation, troubleshooting and low implementation cost.

Harmonization with other standards: MFER are specially utilized to describe the medical waveform data. Other information than waveform data, such as patient demographic data and finding information, etc., should be written using other healthcare standards, e.g. HL7, DICOM®[1)], the ISO/IEEE 11073 series.

In addition, experts in each field should independently develop relevant standards for medical specifications, e.g. MFER for ECG is developed by cardiologists and EEG is developed by neurologists.

Combination with coded information and text information: MFER policy is that both machine and human readable manner are used. Namely coded information is for computer processable and text data are for human readable information. For example, arterial blood pressure (ART) is coded as 129 and information description fields indicate "right radial artery pressure". As the description of MFER is quite flexible, MFER neither hinders the features of each system nor impedes the development of technologies.

1) DICOM is the trademark of a product supplied by Medical Imaging & Technology Alliance, a division of the National Electrical Manufacturers Association. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

Health informatics — Medical waveform format —

Part 1:
Encoding rules

1 Scope

This document specifies how medical waveforms, such as electrocardiogram, electroencephalogram, spirometry waveform, etc., are described for interoperability among healthcare information systems.

This document can be used with other relevant protocols, such as HL7, DICOM®, the ISO/IEEE 11073 series, and database management systems for each purpose.

This is a general specification, so specifications for particular waveform types and for harmonization with DICOM®, SCP-ECG, X73, etc. are not given.

This document does not include lower layer protocols for message exchange. For example, a critical real-time application such as a patient monitoring system is out of scope and this is an implementation issue.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1.1
frame
waveform (3.1.5) encoding unit consisting of data blocks, *channels* (3.1.4) and sequences

Note 1 to entry: The frame in this document is the same as waveform frame.

3.1.2
medical waveform
time sequential data that are sampled by an A/D converter or transmitted from medical equipment

3.1.3
sampling
data that are converted at a fixed time interval

Note 1 to entry: The sampling in this document is the same as waveform sampling.

3.1.4
channel
individual *waveform* (3.1.5) data group

Note 1 to entry: The channel in this document is the same as waveform channel.

3.1.5
waveform
graph showing a change in some physical quantity with time

3.2 Abbreviated terms

A/D	analogue to digital
ECG	electrocardiogram
EEG	electroencephalogram
GPS	global positioning system
HL7	Health Level Seven
DICOM®	Digital Imaging and Communications in Medicine
IEEE	Institute of Electrical and Electronic Engineers
IEC	International Electrotechnical Commission
JIS	Japanese Industrial Standard
LSB	least significant bit
MFER	medical waveform format encoding rules
OID	object identifier
SCP-ECG	Standard Communications Protocol for Computerized Electrocardiography (see EN 1064)
SPO_2	saturation of peripheral oxygen
UID	unique identifier
UUID	universally unique identifier
VCG	vectorcardiogram

4 Basic specifications

4.1 Basic attributes

4.1.1 General

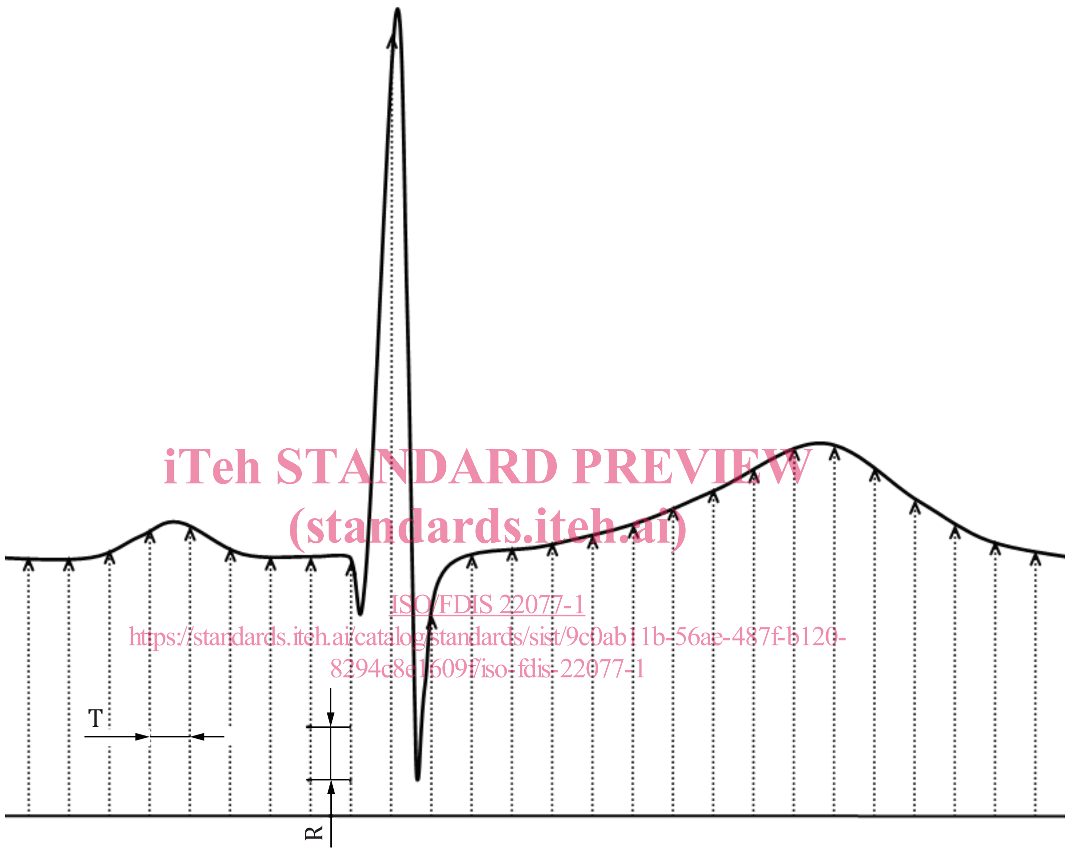
Medical waveform data described in accordance with the MFER consists of sampling attributes (see Figure 1), frame attributes (see Figure 2) and other supplemental information.

4.1.2 Sampling attributes

Sampling information has two attributes: sampling rate and sampling resolution.

a) Sampling rate is described with sampling interval or sampling frequency. The sampling interval stands for the time or distance interval of each sampled data as distributed sampled waveform data.

b) Sampling resolution represents a minimum sampling value per least significant bit (LSB).



Key

T sampling interval (or frequency)

R resolution

Figure 1 — Sampling attributes

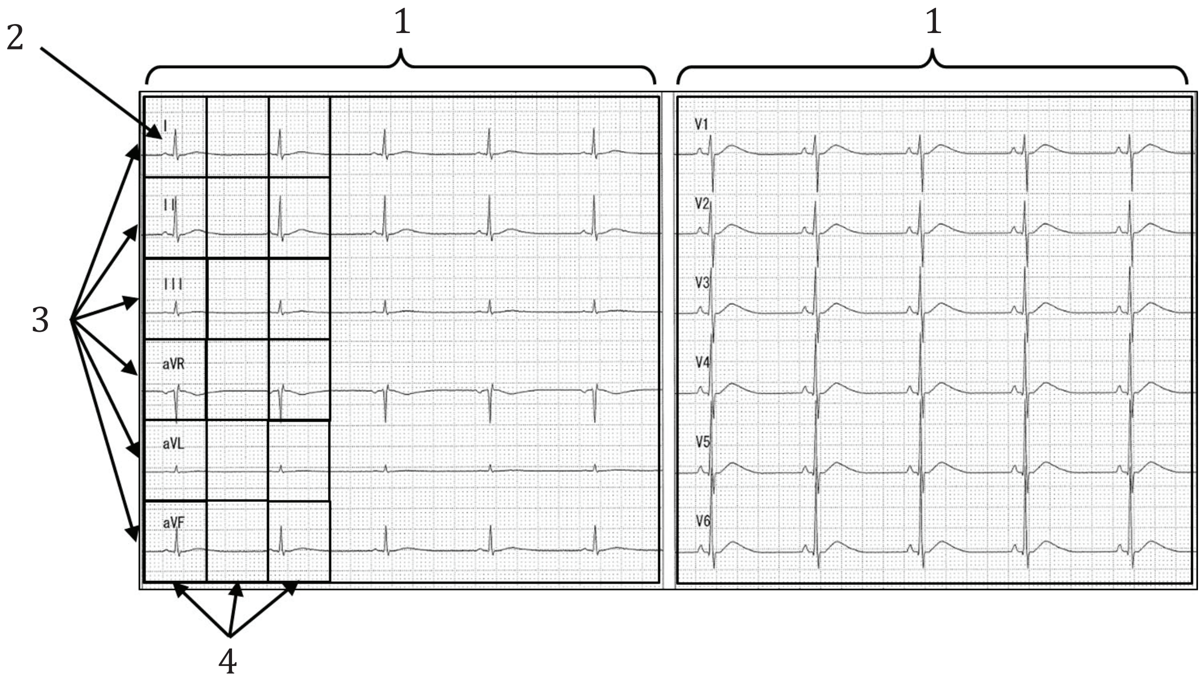
4.1.3 Frame attributes

The frame is a waveform encoding unit consisting of data blocks, channels and sequences. A configuration example of a frame is shown in Figure 2.

a) The data block is the waveform data array for each channel.

b) The channels indicate different waveform groups, e.g. if three waveform groups exist, the number of channels is three.

c) The sequence represents the repetition of the group with the data block and channel.



Key

1 frame

2 data block

3 channel

4 sequence

Figure 2 — Frame attributes

4.2 Encoding rule

4.2.1 General

The header and waveform data should be encoded based on the encoding rules, which are composed of the tag, length and value (TLV), as shown in Figure 3.

— The tag (T) consists of one or more octets and indicates the attribute of the data value.

— The data length (L) is the length of data values indicated in one or more octets.

— The value (V) is the contents which are indicated by tag (T), e.g. attribute definition, waveform data.

Tag (T)	Data length (L)	Value (V)

Figure 3 — Data unit

4.2.2 Tag (T)

The tag is composed of a class, primitive/context (P/C) and tag number. The tag is classified into four classes (see Table 1). Classes 0 to 2 are MFER standard coding and class 3 is for private use. The private definition is intended for special purposes but should be included within any updated future version.

Table 1 — Tag

8	7	6	5	4	3	2	1
Class		**P/C**	**Tag number**				
0	0	0/1	MFER				
0	1						
1	0						
1	1		Private				

a) Primitive type (P/C = 0).

P/C = 0 indicates a primitive description.

b) Context type (P/C = 1).

This has only two tags, which are group and channel definition on current MFER. Figure 4 gives an example of a group definition.

8	7	6	5	4	3	2	1
0	1	1	0	0	1	1	1

Figure 4 — Group definition

4.2.3 Data length (L)

4.2.3.1 General

The data length indicates the number of octets used for data values in the value (V) section (i.e. the length excluding octets used for tag and data length sections). The data length encoding method differs depending on whether the number of octets used for data are less than 127 or more than 128 octets.

4.2.3.2 When the data value section uses 127 octets or less

The length is encoded in one octet, as shown in Figure 5.

8	7	6	5	4	3	2	1
0	Data length						

Figure 5 — Data length ≤ 127 octets

4.2.3.3 When the data value section uses 128 octets or more

The long data length can be encoded using multiple octets. The first octet indicates the number of octets used to represent the total data length. For example, two subsequent octets are used to indicate the waveform data length from 128 to 65 535 and thus three octets are used to encode the data length as shown in Figure 6. However, MFER allow representation of a data length using multiple octets even if the length is less than or equal to 127 octets. For example, four octets can describe up to 4 294 967 295 bytes length as a data part.

8	7 6 5 4 3 2 1	8 7 6 5 4 3 2 1	8 7 6 5 4 3 2 1	8 7 6 5 4 3 2 1
1	Length number (e.g. 3 octets)	Most significant octet	The second octet	The third octet

Figure 6 — Data length

4.2.3.4 Designation of indefinite data length

MFER allow designation of an indefinite data length by encoding 80 h on the top of the data length field (see Figure 7). The indefinite data length is valid only when the waveform data value is described at the end of the file. This indefinite length designation is terminated by encoding the end-of-contents (tag = 00, data length = 00).

Tag P/C = 1	Length (80 h)	- - - - -	- - - - -	- - - - -	End-of-contents (00,00)

Figure 7 — Indefinite length designation and end-of-contents designation

4.2.3.5 When the data length is 0

"Data length 0" indicates that the definition indicated by tag resets to the default value. Namely, on the root definition, the concerned items re-initialize to default values, and in cases of the channel definition, the channel definition is re-initialized to the root definition.

4.2.4 Value (V)

The header or waveform data values are encoded in the value section according to descriptors specified by the tag.

4.3 Encoding principle

4.3.1 General

All definitions in MFER have default values, so any additional or amended definitions are optional. Thus, the definition corresponding to each tag has a default value, so re-definition is not necessary if the default value is retained. It is expected that default definitions will suffice for most purposes.

4.3.2 Definition levels

4.3.2.1 Level 1 — Basic definitions

Definitions at level 1 are basic definitions, which are ordinary rules (marked with an asterisk) and ensure precise encoding.

4.3.2.2 Level 2 — Supplementary definitions

Definitions at level 2 are supplementary definitions. They may be used as required but it is desirable to associate the supplementary definitions with a host protocol where they can be defined with the host protocol.

4.3.2.3 Level 3 — Extended definitions

Definitions at level 3 are extended definitions, which should be used as little as possible. Items of these extended definitions can considerably affect the system with regard to security. Thus, great care should be taken when using them.

4.3.3 General principles in interpretation, scope and priority of definitions

4.3.3.1 Initial values (default value)

All definitions in MFER have initial values that are applied until redefined by any subsequent definition.

4.3.3.2 Multiple definitions

Multiple definitions may be made for any item. Depending on the items, a new definition, an old definition or all definitions (such as for events) can be used multiple times.

For example, setting the sampling frequency to 250 Hz overrides the initial value of 1 kHz.

If multiple events occur, they are interpreted in definition order.

4.3.3.3 Later definition priority

Each definition is interpreted in definition order. If an item has related definitions, definition should be made in due order. The default endianity is big-endian, so to use little-endian endianity the definition for little-endian must be designated.

For example, before defining each channel, the number of channels should be defined.

4.3.3.4 Channel attributes definition order

Before defining the attributes of a channel, the number of channels should be defined. If the number of channels is defined later, previous channel definitions are reset to the root definition including default values.

4.3.3.5 Root definition (general definition) and channel definition (definition per channel)

The root definition is effective for all channels. The channel definition is effective only for the relevant channel and overrides the root definition. However, care should be taken because if a subsequent change to the root definition is made it will override the default content of the relevant channel for subsequent channel definitions.

For example, if EEG is designated in the root definition, ECG designated for a channel in the channel definition overrides EEG.

4.3.3.6 Definition reset

If the data length is defined as zero (no data) in the definition of an item, the content in the definition is reset to default value. If the data length is designated as zero in a channel definition, the definition follows the root definition including the default value. If the number of channels is defined, contents defined for the channel attribute are all reset to the root definition including the default value.

4.3.3.7 Incomplete definition ignored

If a definition is made without an adequate preceding definition, the definition is ignored.

In the absence of any complete definition, the default root definition will be applied.

For example, if the number of channels is undefined, any dependent channel definition is ignored.

4.3.3.8 Succession of definitions

Unless redefined, each definition applies to all succeeding frames in the effective range, except for the data pointer which is succeeding renewed. Thus, contents defined in the root definition apply to all frames unless overridden by channel definition(s), so it suffices to define common items in the root definition.

For example, to use little-endian for all encodings with MFER, define little-endian once, then it is effective over the whole region irrespective of frames.