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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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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*.

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

Harmonization with other standards: MFER is 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, such as HL7, DICOM, ISO/IEEE 11073.

In addition, experts in each field should independently develop relevant standards for medical specifications; for example 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. Arterial blood pressure (ART) is coded as 129 and information description fields indicate "Right radial artery pressure", for example. As the description of MFER is quite flexible, MFER neither hinders the features of each system nor impedes the development of technologies.

Health informatics — Medical waveform format —

Part 1: Encoding rules

1 Scope

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

This International Standard may be used with other relevant protocols, such as HL7, DICOM, ISO/IEEE 11073, 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 International Standard does not include lower layer protocols for message exchange. For example, a critical real-time application like a patient monitoring system is out of scope and this is an implementation issue.

2 Terms and definitions

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

2.1
frame
waveform encoding unit consisting of data blocks, channels, and sequences

2.2
medical waveform
time sequential data that are sampled by A/D converter or transmitted from medical equipment

2.3
sampling
data that are converted at a fixed time interval

2.4
channel
individual waveform data group

3 Abbreviated terms

AAMI	Association for the Advancement of Medical Instrumentation
A/D	Analog to Digital
CSE	Common Standards for Quantitative Electrocardiography
CEN	Comité Européen de Normalization/European Committee for Standardization
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
MSB	Most significant bit
OID	Reference to the ISO standard.
SCP-ECG	Standard Communications Protocol for Computerized Electrocardiography (EN 1064)
SPO_2	Saturation of Peripheral Oxygen
UID	Reference to the ISO standard
UUID	Reference to the ISO standard
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 (Figure 1), Frame attributes (Figure 2) and other supplemental information.

4.1.2 Sampling attributes

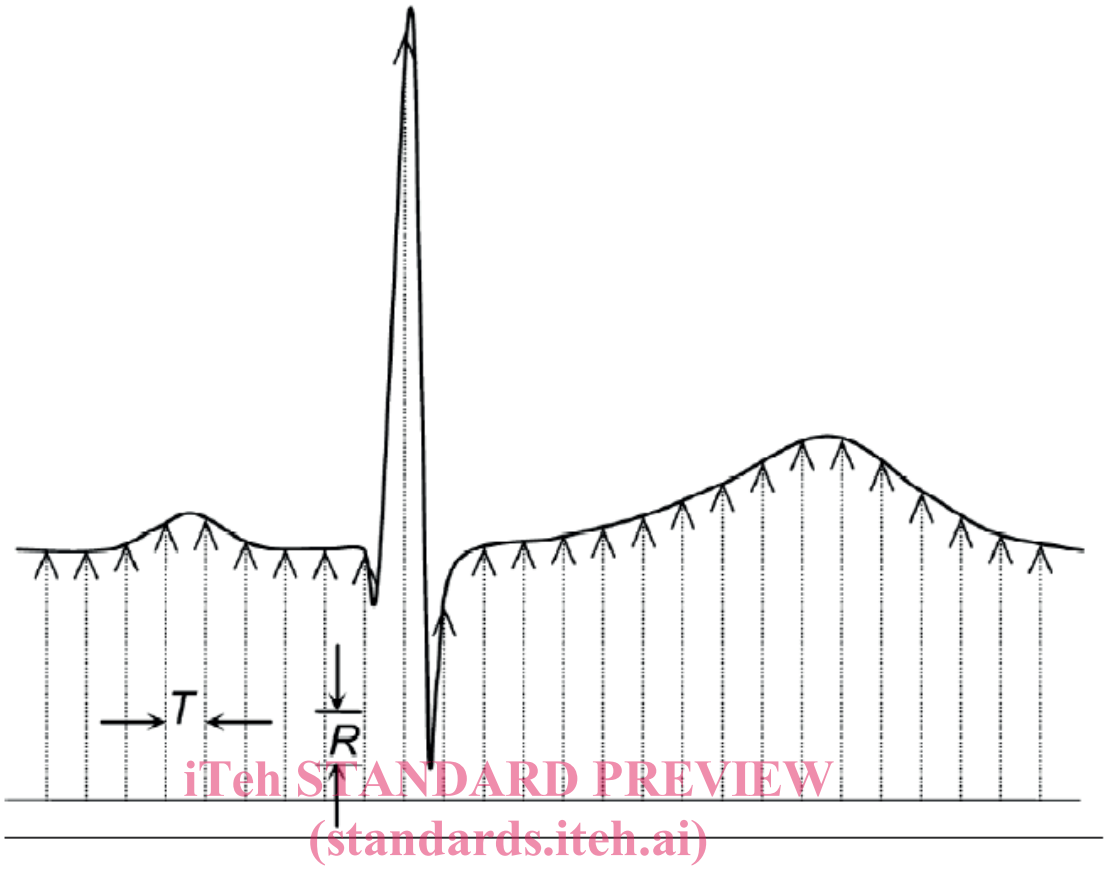
Sampling information has two attributes, sampling rate and sampling resolution.

a) sampling rate

The 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

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 as Figure 2.

a) data block

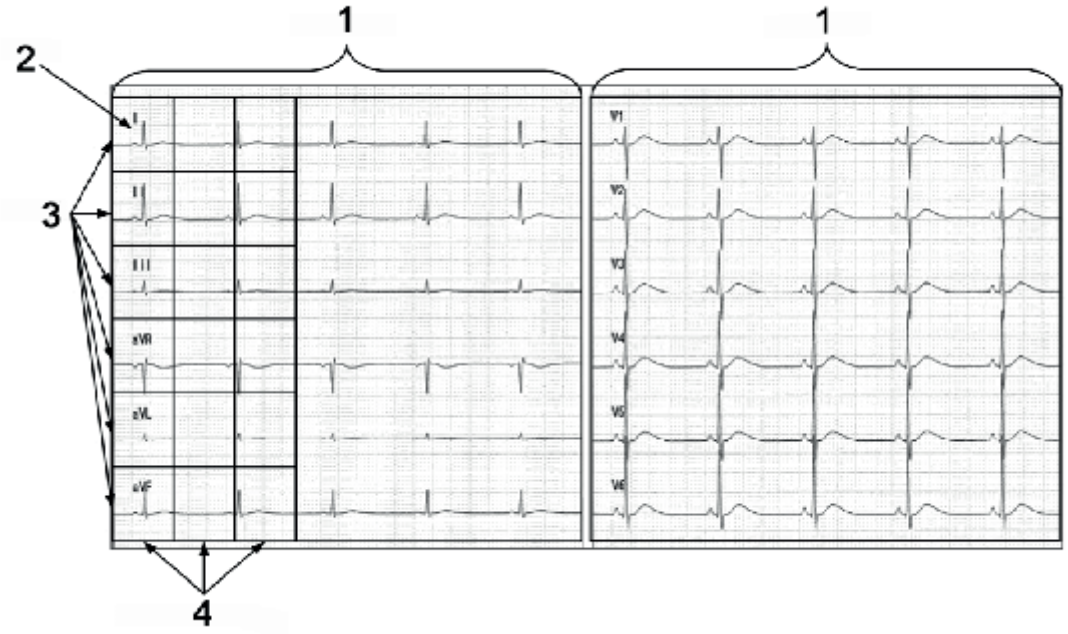
The data block is the waveform data array for each channel.

b) channels

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

c) sequence

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.

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

Figure 3 — Data unit

— 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) are the contents which are indicated by tag (T); e.g. attribute definition, waveform data, etc.

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 (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)

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.

a) In case 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

b) In case 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 in Figure 6. However, MFER allows representation of a data length using multiple octets even if the length is less than 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

c) Designation of indefinite data length.

MFER allows designation of an indefinite data length by encoding 80 h on the top of the data length field (Figure 7). This indefinite length designation is terminated by encoding the end-of-contents (tag = 00, data length = 00).

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

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

d) In case the data length is 0.

MFER 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 case 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 may considerably affect the system with regard to security. Thus, great care should be taken in 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 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.

4.3.3.9 Definition and efficacy of data

It depends on the functional capability of the user application whether or not the user can use data defined by the provider. If some content cannot be processed, users may discard all the data or use only the processable range of data.

5 Basic rules (Level 1)

5.1 Primary description

5.1.1 Sampling attributes

Sampling attributes are sampling frequency or sampling interval and resolution are given in Tables 2 to 5.

a) **MWF_IVL (0Bh): Sampling rate**

This tag indicates the frequency or interval the medical waveform is sampled (Table 2).

Table 2 — Sampling rate

MWF_IVL*			Data length	Default	Encoding range/ remarks	Duplicated definitions
11	0Bh	Unit	1	1 000 Hz	—	Override
		Exponent (10^{th} power)	1		10^{-128} to 10^{+127}	
		Mantissa	≤4		e.g. unsigned 16-bit integer	

The unit may be frequency in Hertz, time in seconds or distance metres (Table 3).

Table 3 — Sampling rate unit

Unit		Value	Remarks
Frequency	Hz	0	Including power
Time interval	s	1	—
Distance	m	2	—

b) **MWF_SEN (0Ch): Sampling resolution**

This tag indicates the resolution, minimum bits, the medical waveform is sampled (generally, digitized) (Table 4).

Table 4 — Sampling resolution

MWF_SEN*			Data length	Default	Encoding range/ remarks	Duplicated definitions
12	0Ch	Unit	1	see Table 5	—	Override
		Exponent (10^{th} power)	1		10^{-128} to 10^{+127}	
		Mantissa	≤4		e.g. unsigned 16-bit integer	

Table 5 — Sampling resolution units

Unit		Value	Default	Remarks
Voltage	V	0	0,000 001 V	—
Pressure	mm Hg(Torr)	1	—	—
	Pa	2	—	—
	cm H_2O	3	—	—
	mm Hg/s	4	—	—
Force	dyne	5	—	—
	N	6	—	—
Ratio	%	7	—	Include volume fraction (%)
Temperature	°C	8	—	—
Heart rate	min^{-1}	9	—	—
	s^{-1}	10	—	—
Resistance	Ω	11	—	—
Current	A	12	—	—
Rotation	r/min	13	—	—
Power	W	14	—	—
	dB	15	—	—
Mass	kg	16	—	—
Work	J	17	—	—
Vascular resistance	dyne · s · $m^{-2}cm^{-5}$	18	—	—
Flow rate, flow, volume	l	19	—	—
	l/s	20	—	—
	l/min	21	—	—
Luminous intensity	cd	22	—	—

5.1.2 Frame attributes

As described in Figure 2 a frame is composed of data blocks, channels and sequences.

a) MWF_BLK (04h): Data block length

This tag indicates the number of data sampled in a block (Table 6).

Table 6 — Data block length

MWF_BLK*		Data length	Default	Remarks	Duplicated definitions
04	04h	≤ 4	1	—	Override

b) MWF_CHN (05h): Number of channels

This tag indicates the number of channels (Table 7). As the previously specified channel attribute is reset to the root definition including default, the number of channels should be specified before each definition of the channel attribute. The number of channels cannot be specified with a channel definition of channel attribute.