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Health informatics — Medical waveform format —

Part 92001: Encoding rules

*Informatique de santé — Forme d'onde médicale —
Partie 92001: Règles d'encodage*



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Foreword

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An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

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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: MEFR 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. ART (arterial blood pressure) 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.

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Health informatics — Medical waveform format —

Part 92001: Encoding rules

1 Scope

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

This Technical Specification 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 Technical Specification 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 Normalisation/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
SCP-ECG	Standard Communications Protocol for Computerized Electrocardiography (EN 1064)
SPO2	Saturation of Peripheral Oxygen
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

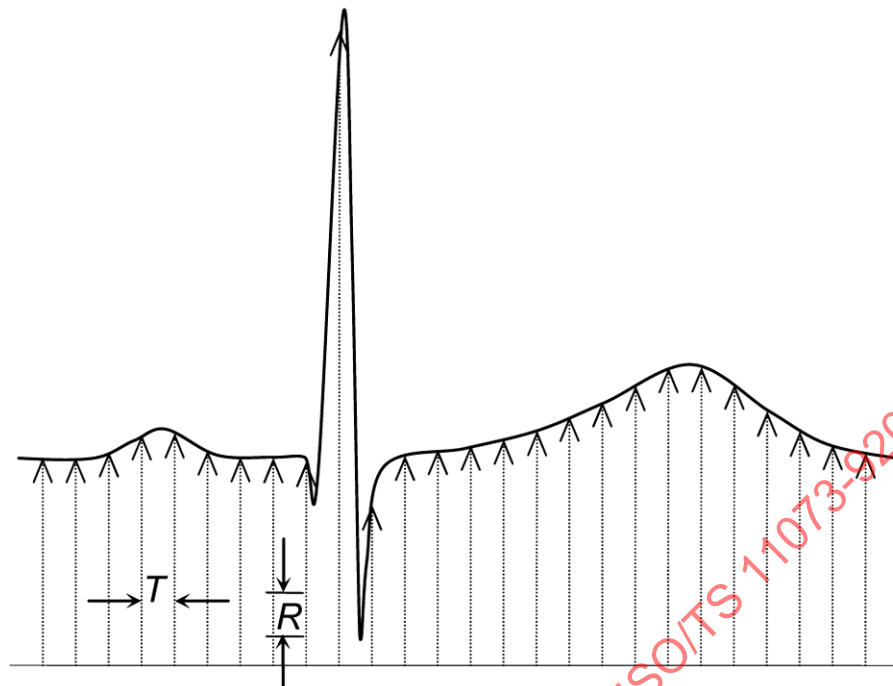
Sampling information has two attributes, sampling rate and sampling resolution.

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

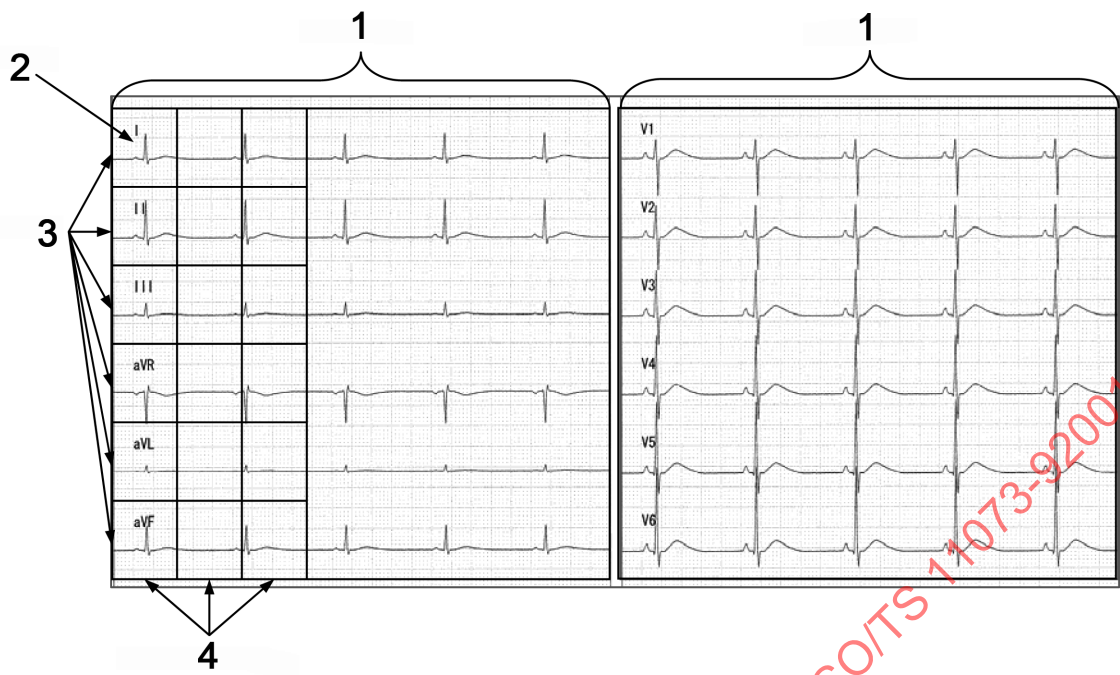
The data block is the waveform data array for each channel.

b) Channels

The channels indicate different waveform groups, e.g. if three waveform groups exist, the number of channels is 3.

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) is 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 is 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 privacy, security, etc.; 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), may 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 endianness is big-endian, so to use little-endian endianness 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 examples, 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.

1) 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. signed 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	—

2) 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. signed 16-bit integer	

Table 5 — Sampling units

Unit		Value	Default	Remarks
Voltage	V	0	0,000 001 V	—
Pressure	mm Hg(Torr)	1	—	—
	Pa	2	—	—
	cm H ₂ O	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.

1) 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

2) 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.

Table 7 — Number of channels

MWF_CHN*		Data length	Default	Remarks	Duplicated definitions
05	05h	≤ 4	1	—	Override

3) MWF_SEQ (06h): Number of sequences

This tag indicates the number of sequences (Table 8). If the number of sequences is not designated, it depends on the data block length, the number of channels and the number of waveform data values which are defined for the concerned frame.

Table 8 — Number of sequences

MWF_SEQ*		Data length	Default	Remarks	Duplicated definitions
06	06h	≤ 4	Depends on waveform data length	—	Override

5.1.3 Waveform

The waveform type, waveform attributes and waveform data are encoded as follows.

1) MWF_WFM (08h): Waveform class

Waveforms such as standard 12-lead ECG and monitoring ECG are grouped based on instruments and purposes, as shown in Table 9.

Table 9 — Waveform class

MWF_WFM*		Data length	Default	Remarks	Duplicated definitions
08	08h	2	Non-specific waveform	—	Override
		Str ≤ 32	Waveform description	—	

As a general rule, standardization will be made by type of waveforms, each is described in a separate specification (e.g. for standard 12-lead ECG 11073-92301). However, because monitoring systems use multiple waveforms such as ECG, SpO2, EEG, etc., refer to the specification for each individual waveform standard.

For types of waveform (Table 10), numbers 1 to 49151 (BFFFh) are already reserved. Numbers 49152 to 65535 may be used privately but it should be documented in the MFER specification as quickly as possible if the waveform is commonly used.

2) MWF_LDN (09h): Waveform attributes (lead name, etc.)

Code and information can be added to the type of waveform. If a waveform is required to be reconfigured, as in the case of deriving leads III and aVF from leads I and II, the codes should always be specified. The codes should be taken into special consideration as they have a function to specify some processing, as in the case of deriving other limb leads from leads I and II or deriving a waveform based on the lead name. See Table 11 for the definition of waveform attributes.

As the lead names are defined depending on the class of waveform, they are not consolidated throughout each class of waveform in MFER. Thus, caution should be taken in encoding lead names.

For waveform codes, numbers 1 to 49151 (BFFFh) are already reserved. Numbers 49152 to 65535 may be used privately but should be used for new types of waveforms by upgrading the MFER promptly.

Table 10 — Classification of waveforms

Classification	Type	Value	Description	Reference	Remarks
—	—	0	Unidentified	—	—
Electrocardiogram	ECG_STD12	1	Standard 12 lead ECG	Part 3-1	Different kinds of 12 lead ECGs including general ECGs can be encoded
	ECG_LTERM	2	Long-term ECG	Part 3-2	Holter ECG, monitoring ECG
	ECG_VECTR	3	Vectorcardiogram	Part 3-5	—
	ECG_EXCER	4	Stress ECG	Part 3-3	—
	ECG_INTR	5	Intracardiac ECG	Part 3-4	His bundle ECG, intracardiac ECG, intravascular ECG, cardiac surface ECG
	ECG_SURF	6	Body surface ECG	Part 3-5	Body surface potential map Body surface His bundle ECG
	ECG_ILATE	7	Ventricular late potential	Part 3-5	—
	ECG_LATE	8	Body surface late potential	Part 3-5	—
Sound	SOUND	30	PCG, etc.	Part 3-13	8 kHz, 11 kHz, 22 kHz, etc.
Pulse	PULSE	31	Fingertip pulse, carotid pulse	Part 3-14	—
Monitoring	MON_LTRM	20	Long-term waveform	Part 3-10	—
	MON_SPL	21	Sampled waveform	Part 3-10	—
	MON_PWR	25	Power spectrum	Part 3-9	Some part is EEG_CSA
	MON_TRD	26	Trendgram	Part 3-11	—
Magnetocardiogram		100	MCG	Part 3-12	—
Electroencephalogram	EEG_REST	40	Resting EEG	Part 3-6	Includes surgical monitoring EEG
	EEG_EP	41	Evoked EEG	Part 3-7	ABR SEP
	EEG_CSA	42	Frequency analysis	Part 3-8	—
	EEG_LTRM	43	Long-term EEG	Part 3-6	Sleeping EEG
Private	49152 to 65535		—	—	—

Table 11 — Definition of waveform attributes

MWF_LDN *			Data length	Default	Data range, remarks	Duplicated definitions
09	09h	Waveform code	2	Unidentified	Data length = 2, if waveform information is encoded	Override
		Waveform information	Str ≤ 32		—	

EXAMPLE Standard 12-lead ECG code, shown in Table 12.

Mainly, standard 12-leads are encoded according to the SCP-ECG (EN 1064) or annotated ECG coding system, but some leads are not defined the same as SCP-ECG.

Table 12 — Lead code of standard 12 lead ECG

Code	Lead	Code	Lead
1	I	13	V5R
2	II	14	V6R
3	V1	15	V7R
4	V2	61	III
5	V3	62	aVR
6	V4	63	aVL
7	V5	64	aVF
8	V6	66	V8
9	V7	67	V9
11	V3R	68	V8R
12	V4R	69	V9R

EXAMPLE Monitoring aortic pressure waveform.

Encoding monitoring waveform information.

Table 13 — Blood pressure waveform (Aortic blood pressure waveform)

Waveform code	Waveform information	Remarks
128	—	Coded value indicates as “Aortic pressure”
129	“Aorta”	Coded value indicates as “Arterial pressure” and Information description part indicates “Aorta”
143	“Aorta”	Coded value only indicates as “Pressure” and Information description part indicates “Aorta”

EXAMPLE Electroencephalogram waveform.

Generation of waveform codes by combination of electrodes (see Figure 8).

16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
0	1	– negative electrode (G1)							+ positive electrode (G2)						

Figure 8 — Generation of waveform code by combination of electrodes

Waveform codes can be generated by combination of electrode codes, as shown in Table 14 and Table 15.

Table 14 — Electrode code (refer to Part 3-6 for full details)

Name	Abbreviation	Electrode code
Left front polar	FP1	12
Right front polar	FP2	13
Left ear	A1	74
Right ear	A2	75

Table 15 — Example of waveform code generation

Lead	– electrode	+ electrode	Waveform code
FP1 - A1	12	74	17994(464A)
FP2 - A2	13	75	18123(46CB)

3) MWF_WAV (1Eh): Waveform data

The entity of waveform data should strictly be aligned as defined in Frame attributes (4.1.3). If the waveform data is compressed, the data alignment may depend on the compression method, but the waveform data after un-compressing should be aligned according to the definition. See Table 16.

If waveform data are different from what is defined in frame information, exceeding data may be discarded. However, such processing depends on application and it is not guaranteed.

Table 16 — Waveform body

MWF_WAV		Data length	Default	Remarks	Duplicated definitions
30	1Eh	waveform	Waveform length	—	—

5.1.4 Channel

1) MWF_ATT (3Fh): Channel attributes (channel definition)

This tag defines the attributes of each channel (see Table 17). Before this definition, it should be required to specify the channel number using Table 7.

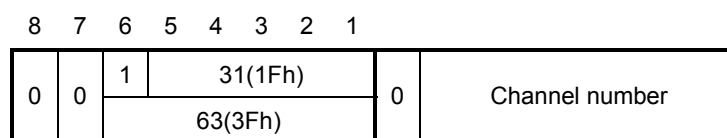
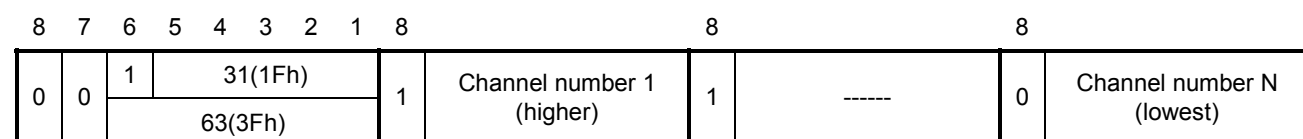
The method of encoding a channel number differs depending on whether it is ≤ 127 or ≥ 128 . Refer to Figure 10 for ≤ 127 and to Figure 11 for ≥ 128 .

Table 17 — Channel attributes

MWF_ATT*	Data length	Default	Remarks	Duplicated definitions
63	3Fh	Depends on definition	—	Override

NOTE Channel definition for each channel is encoded with a special context tag of P/C = 1 and tag number of 1Fh. That is, the type number is P/C + tag number encoded with 3Fh and identifies the attribute of the relevant channel. The channel number is identified with seven bits in the octet with bit 8 = 0 for up to 127 channels and with bit 8 = 1 for 128 or higher channel number.

For the tag of the channel attribute definition, context mode is selected with P/C (bit 6 = 1).

**Figure 9 — Number of channel ≤ 127** **Figure 10 — Number of channel ≥ 128**

The data length includes all the range of the channel attribute definition (Figure 11).

Tag		Data length	Group of definition									
3Fh	Channel number	All definition	Channel attribute definition			Channel attribute definition			----	Channel attribute definition		
			T	L	V	T	L	V	—	T	L	V

Figure 11 — Definition of channel attributes

The indefinite length described in Figure 7 can be used for the channel attribute definition (Figure 11 and Figure 12).

Tag		Data length	Group of definition									
3Fh	Channel number	80h	Channel attribute definition			Channel attribute definition			-----		End-of-contents	
			T	L	V	T	L	V	—		00	00

Figure 12 — Definition of channel attributes with indefinite length

5.2 Auxiliary rule

5.2.1 Data description

1) MWF_DTP (01h): Data type

This tag indicates the type of waveform data (Table 18 and Table 19). While medical waveforms are usually sampled with a precision of 12 bits, by default they are all interpreted and encoded as 16-bit data.

Table 18 — Data type

MWF_DTP		Data length	Default	Remarks	Duplicated definitions
10	0Ah	1	Signed 16-bit integer	—	Override

Table 19 — Data type code

Value	Type of data
0	Signed 16 bits integer, -32768 to 32767
1	Unsigned 16 bits integer, 0 to 65535
2	Signed 32 bits integer
3	Unsigned 8 bits integer
4	16 bits status
5	Signed 8 bits integer
6	Unsigned 32 bits integer
7	32 bits single-precision floating (IEEE754)
8	64 bits double-precision floating (IEEE754)
9	8 bits AHA differential

2) MWF_OFF (0Dh): Offset value

This tag indicates an offset value (Table 20) of sampling data. Encoding of an offset value depends on the type of encoding data.

Table 20 — Offset value

MWF_OFF		Data length	Default	Remarks	Duplicated definitions
13	0Dh	≤ 8 (depends on types of encoding data values)	0	—	Override

3) MWF_NUL(12h): NULL value

This tag indicates null data. If null values (Table 21) are included in waveform data, the waveform datum is ignored even if it exists. As null data use the same encoding space as waveform data, the tag should be used carefully. For example, a minimum negative value 8 000 h is occasionally used for a null value. If the null values are encoded during a period in which the electrode is removed, ECG is not displayed. Encoding of a null value depends on the type of encoding data.

Table 21 — Null value

MWF_NUL		Data length	Default	Remarks	Duplicated definitions
18	12h	≤ 8 (depends on types of encoding data values)	Unused	—	Override

4) MWF_CMP (0Eh): Compression

This tag is to compress the encoding waveform.

Table 22 — Compression

MWF_CMP			Data length	Default	Remarks	Duplicated definitions
14	0Eh	Compression code	2			
		Data length	4		Data before compression	
		Compressed data	Data length after compression		Compressed data	

MFER enables encoding of waveforms by compressing (Table 22). This improves the efficiency of encoding capacity but makes the processing speed decrease, so sufficient consideration should be made when compressing. If compression is specified with this tag (MWF_CMP), data in the header section or waveforms in the data section are all compressed thereafter. Compressed data block length and channels in sequences may not be available depending on compression methods (Table 23) but the encoded frame information returns after decompression.

Table 23 — Compression method

Compression ID	Compression method	Description
0	No compression	No compression applied to data encoding (default)
2	MFER	Compression applied to header section
3		Compression applied to waveform data section

Compressed data methods for headers and waveforms are given in Table 24 and Table 25 respectively.

Table 24 — Compression applied to header section

Tag	0Eh
Data length	Length of whole data section
Compression code	2
Data before compression	Length of data before compression
Compressed data (header)	Compressed data (data of header)

Table 25 — Compression applied to waveform data

Tag	0Eh
Data length	Length of whole data section
Compression code	3
Data before compression	Length of data before compression
Compressed data (waveform data)	Compressed data waveform data

5.2.2 Other definition

1) MWF_BLE (01h): Endianity

This tag indicates byte alignment in the data section (TLV values only). The big-endian is aligned byte data from most significant to least significant. This is used by Sun Microsystems® and Macintosh CPUs. The little-endian is aligned from least significant to most significant. This is used by Intel® and other 'PC' CPUs. See Table 26 and Table 27.

Table 26 — Endianity

MWF_BLE		Data length	Default	Remarks	Duplicated definitions
01	01h	1	Big-endian	—	Override

Table 27 — Big/Little endian

Endianity	
0	Big-endian
1	Little-endian

However, irrespective of the specification by this tag, the tag and data length field are processed in the network alignment (big-endian).

2) MWF_PNT (07h): Pointer

This tag indicates the waveform data pointer, which is represented by the sampling rate of the root level, in the frame. If no pointer is designated, the pointer of the first frame is initialized as zero (Table 28). The pointer for the next frame is deemed to be a value adding the number of data length of the virtual root level channel in the previous frame.

For example, if no pointer is specified for the first frame with the sampling interval set at 2 ms, and the number of waveform length for each channel set at 1 000, and the number of sequences set at 1 in the root definition, then the initial pointer of the second frame advances by 2 s (1 000 data values × 1 sequence of 2 ms).

Table 28 — Pointer

MWF_PNT		Data length	Default	Remarks	Duplicated definitions
07	07h	≤ 4	Zero or pointer of previous frame	—	Override

3) MWF_ZRO (00h): Blank/End-of-contents

Usually, a blank tag is not analysed. This tag also indicates the end of the indefinite length if designated, together with data length = 0. End-of-contents (Table 29) need succeed two zero as explained in Figure 7.

Table 29 — Blank or end-of-contents

MWF_ZRO		Data length	Default	Remarks	Duplicated definitions
00	00h	1	—	—	Multiple use possible

5.2.3 Information description

1) MWF_PRE (40h): Preamble

This tag for a special purpose is encoded at the heading of a file to indicate the attributes of the entire MFER waveform file and data. The MWF_PRE is fixed in length. The classification is in four characters (MFR +space) and description is in a fixed number of 28 characters. Blank fields, if any, are to be filled with 00h or space (20h). See Table 30.

Table 30 — Preamble

MWF_PRE		Data length	Default	Remarks	Duplicated definitions
64	40h	4	—	"MFR "	To be encoded at the head
		28		28 characters	

EXAMPLE Preamble information:

"MWF_PRE 0x20 MFR Standard 12 leads ECG" is equal to "@ MFR Standard12 leads ECG".

2) MWF_MAN (17h): Manufacturer information of medical device

This tag indicates the information on the manufacturer, model and version number of the medical waveform generating machine with a component separator in between. See Table 31.

Table 31 — Manufacturer information

MWF_MAN		Data length	Default	Remarks	Duplicated definitions
23	17h	Str ≤ 128	none	—	Override

EXAMPLE Description sample:

Manufacturer^model^version number^serial number.

3) MWF_EVT (41): Event

This tag is to encode supplementary waveform information such as events. (Refer to Annex C.) See Table 32.

— Beat annotation: for classification of waveforms, etc.

— Interpretation: for interpretation of relevant waveform.

Table 32 — Event

MWF_EVT			Data length	Default	Encoding range/remarks	Duplicated definitions
65	41h	event code	2	None		Possible
		Starting time (point)	4		Number of data values acquired at the sampling interval defined in the root definition	
		Duration	4			
		Event information	Str ≤ 256			

4) MWF_INF (15h): Waveform information

This tag indicates waveform information which is generated (refer to Annex C), for example, catheter information to measure cardiac output by dye dilution method. See Table 33.

Table 33 — Waveform information

MWF_INF			Data length	Default	Data range/remarks	Duplicated definitions
21	15h	Information code	2	—	—	Possible
		Starting time (point)	4		Point number based on the sampling interval specified in the root definition	
		Duration	4			
		Waveform information	Str ≤ 256			

5) MWF_CND (44h): Acquisition or processing information

This tag represents the acquisition condition or processing information during the waveform acquisition processing. For example, if the EEG waveforms are stored in original form but displayed with a montage during examination, the montage is represented with this tag to reproduce the integrity with combination electrodes. See Table 34.

Table 34 — Recording/Display condition

MWF_CND			Data length	Default	Remarks	Duplicated definitions
68	44h	Acquisition condition	2	—	—	—
		Description code 1	2			
		Description code 2	2			
		Starting point	4			
		Duration	4			
		Descriptive information	Str ≤ 256			

MFER requires faithful reproduction of waveforms. For example, the waveform was displayed during measurement using some filters, but the waveform in MFER coding is stored in unprocessed form as far as possible and filter or montage information are described in this tag. The contents for expected faithful reproduction are encoded with description codes 1 and 2. The conditions are provided in the waveform specifications (Part 3).

6) MWF_NTE (16h): Comment

This tag represents a memo or comment. It does not directly affect encoding of waveforms.

Information affecting waveforms is encoded using the MWF_INF tag (waveform information).

Table 35 — Comment

MWF_NTE		Data length	Default	Remarks	Duplicated definitions
22	16h	Str ≤ 256	—	—	Possible

A comment should be encoded within 256 characters but multiple comments may be written as required. Whether a comment has meaning or not depends on the user's system. A long comment can be written by using this tag the required number of times.

By using a special control code, the content of a comment can be given a specific meaning to indicate details to computers, as shown in Table 36.

The control sentence structure is <control character = control information>. For example "<C = 2><P = 100> abnormal waveform observed" is a comment indicating that an abnormal waveform is observed at the pointer position of 100 in the second channel of the concerned frame. <L = 1 FP1-A1> indicates that a lead between FP1 and A1 was recorded in the EEG lead channel 1. <F LP = 50> indicates that the waveform was recorded with the low-pass filter set at a cut-off frequency of 50 Hz.

Table 36 — Control character definitions

Control character	Meaning	Remarks
<	The start of control sentence structure	Control sentence continues until closed with the control character (>)
>	The end of control sentence structure	—
C	Channel	Indicates the channel number
L	Lead	Indicates a lead of ECG, EEG, etc. Depends on lead composition
P	Pointer	Indicates a position (pointer) of waveform
F	Filter	Applied filter
S	Sensitivity	Recording sensitivity
\	Backslash "\"	A character following \ is not recognised as a control character

7) MWF_VER (02h): Version

A version is composed of three parts (three octets) (Table 37).

Precaution: versions should be managed by taking into sufficient consideration the compatibility between old and new versions.

In referring to the data written in an old version with a new version, the old specification is assured securely. In referring to the database of a new version with an old version, the specification of the old version is assured.

Table 37 — Version

MWF_VER		Data length	Default	Remarks	Duplicated definitions
02	02h	1	0	Main version	Override
		1	0	Sub version	
		1	0	Revision history	

8) MWF_TXC (03h): Character code

As shown in Table 38, this tag enables designation of the character code (Table 39) used for the text (e.g. ISO 2022 for Japanese text). If text is written with no character code specified, it is not assured whether users can process the text or not.

Table 38 — Character code system

MWF_TXC		Data length	Default	Remarks	Duplicated definitions
03	03h	Str ≤ 16	ASCII	—	Override

For the structure and meaning of each coding system, refer to the proper specification.

Table 39 — Character code

Character code	Note	Description
JIS X 0201	Japanese katakana	Code for Information Exchange (ISO-IR 13):1976
	Japanese romaji	Code for Information Exchange (ISO-IR 14):1976
JIS X 0208	Japanese kanji, hiragana, katakana	Code for the Japanese Graphic Character set for information interchange (ISO-IR 87):1990
JIS X 0212	Japanese kanji	Code of the supplementary Japanese Graphic Character set for information interchange (ISO-IR 159):1990
RFC 1468	Japanese characters for internet	Japanese Character Encoding for Internet Messages
ISO 2022	—	ISO/IEC 2022:1994, <i>Information technology — Character code structure and extension techniques</i>
ISO 8859	—	<i>Information technology — 8-bit single-byte coded graphic character sets — Parts 1-9 for ISO-IR 100, 101, 109, 110, 144, 127, 126, 138 and 148</i>
ANSI X3.4	—	1986 ASCII character set
ISO 646	—	1991 <i>Information technology — ISO 7-bit coded character set for information interchange</i>
ISO 2375	—	2003, <i>Information technology — Procedure for the registration of escape sequences and coded character sets</i>
ISO/IEC 6429	—	1992, <i>Information technology — Control functions for coded character sets</i>
ENV 41 503	—	1990 Information systems interconnection — European graphic character sets and their coding
ENV 41 508	—	1990 Information systems interconnection — East European graphic character sets and their coding
UNICODE	UTF-8	The world wide character standard from ISO/IEC 10646:2003

9) MWF_FLT (11h): Filter

This tag indicates the filter name which is used during MFER waveform data recording.

NOTE It is recommended to store original waveforms if possible. If display or recording during measurement uses a filter, MFER describes the filter with waveform information.

Table 40 — Filter

MWF_FLT		Data length	Default	Remarks	Duplicated definitions
17	11h	Str ≤ 256	unused	—	Possible

As shown below, a filter or the characteristic is encoded as a character string. It is desirable to define the details through negotiation with users. Recently sophisticated digital filters have been developed, the characteristic of these filter cannot be represented commonly. Therefore, only information on filters used during acquisition of waveform may be represented, as shown in Table 40.

EXAMPLE Filter name

- Hum filter ON
- 30 Hz second order Butterworth low pass
- Chebycheff
- Elliptic

10) MWF_IPD (0Fh): Interpolation or decimation

When encoding the waveform through interpolation or thinning-out, the fact is designated with this tag, shown in Table 41, using the interpolation/decimation codes shown in Table 42.

Table 41 — Interpolation or decimation

MWF_IPD			Data length	Default	Remarks	Duplicated definitions
15	0Fh	Code	1	unused	—	—
		Supplementary information	2		—	

Table 42 — Interpolation/decimation codes

Name	Code	Supplementary description
Unconditional decimation	1	—
Unconditional interpolation	2	—
Lagrange's interpolation	3	Order
Spline interpolation	4	Order
Linear interpolation	5	—
Average	6	Number of averaging times

6 Supplemental description (Level 2)

1) MWF_VAL (42h): Value (measurements, etc.)

This tag represents waveform-related information such as measurements.

Table 43 — Value

MWF_VAL			Data length	Default	Encoding range/remarks	Duplicated definitions
66	42h	Value code	2	None	—	Multiple definitions available
		Time point	4		Number of data values sampled is encoded	
		value	Str ≤ 32		Value is encoded with a character string with unit ("^")	

EXAMPLE Measurement value

If a heart beat is found at the concerned time,

MWF_VAL heart rate code (provided in the specification for each waveform)

Point = – 1 indicates in the whole region of the frame.

"80^/min" Heart rate is 80 bpm.

"120^mmHg" Blood pressure is 120 mmHg.

2) MWF_SKW (43h): Sampling skew

This tag represents the time skew between channels by A/D conversion. Though the most recent devices may not require the designation of such a time skew, it may be designated as required, shown in Table 44.

Table 44 — Sampling skew

MWF_SKW		Data length	Default	Remarks	Duplicated definitions
67	43h	2	0	Time skew between channels is encoded in ns	Override

3) MWF_SET (67h): Group definition

This tag represents a group such as ROI (Region of interest). For example, it clearly defines the P-QRS-T (Einthoven deflections) beat in ECG, shown in Table 45.

Table 45 — Group definition

MWF_SET		Length	Default value	Remarks	Override
103	67h	Depend on definition	—	—	Not available with in same group

4) MWF_UID (87h): Object identifier

This tag indicates UID (Unique Identifier), shown in Table 46.

Table 46 — Object identifier

MWF_UID		Length	Default value	Remarks	Override
135	87h	Str ≤ 64	No	—	No

Description of the Object Identifier (OID) is not be defined by the MFER. This is designated with OID, UUID (Universally Unique Identifier) or other specifications.

5) MWF_MAP (88h): Description map

A Description map (File pointer) can improve processing efficiency by describing a large capacity file in accordance with the MFER (see Table 47). This description cannot be assured, as it depends on the application.

Table 47 — Description map

MWF_MAP			Length	Default value	Remarks	Override
136	88h	Tag 1	1	No	Data length is used as $6 \times N$ Tag(MWF_ZRO) is not used	Override
		Reserved 1	1			
		File pointer 1	4			
		Tag 2	1			
		Reserved 2	1			
		File pointer 2	4			
		---	—			
		---	—			
		---	—			
		Tag N	1			
		Reserved N	1			
		File pointer N	4			

The file pointer should be described by an unsigned 32-bits integer.

6) MWF_END (80h): End of description

This tag indicates an end of data description (Table 48).

Table 48 — End of description

MWF_END		Length	Default	Remarks	Override
128	80h	Undefined	—	—	

NOTE All data after this tag are ignored.

7) MWF_RPT (45h): Reference pointer

This tag indicates an external reference file pointer represented as a hyperlink (Table 49).

Table 49 — Reference pointer

MWF_SIG			Length	Default	Remarks	Override
69	45h	Data class	1	—		Possible
		Reference pointer	$\text{str} \leq 256$		Represent as URL	

Attributes of data class are shown in Table 50.

Table 50 — Attribute of data class

Data class	Value
Undetermined data format	0
MFER Data	1

8) MWF_SIG (46h): Digital signature

This tag indicates a digital signature (Table 51).

Table 51 — Digital signature

MWF_SIG			Length	Default	Remarks	Override
70	46h	Signature method	1	—	—	No
		Hash value	≤ 256			

7 Extended description (Level 3)

The extension tags are for the extended supplemented information with MFER. This information should preferably be represented with a system standard applicable to the most widespread convention in the usage of the particular implementation of MFER. Such local conventions may be, for example, HL7, DICOM, and so on. The handling of patient demographic information should take in other local considerations and in particular privacy and security.

1) MWF_PNM (81h): Patient name

This tag represents a patient name (Table 52). It is recommended to encode a patient name as follows.

Family name^^first name^^middle name

NOTE (Japanese):family name^family name (furigana)^first name^first name(furigana)^middle name^middle name(furigana).

Table 52 — Patient name

MWF_PNM		Data length	Default	Remarks	Duplicated definitions
129	81h	Str ≤ 128	None	—	Override

2) MWF_PID (82h): Patient ID

This tag identifies a patient identification number (Table 53). The way of using and managing patient ID numbers is beyond the scope of MFER. It is recommended to encode a patient identification number as follows.

Patient ID^Local ID^Temporary ID

If no separator("^") is used, patient ID data is processed as a unique ID in the system.

Table 53 — Patient ID

MWF_PID		Data length	Default	Remarks	Duplicated definitions
130	82h	Str ≤ 64	None	—	Override

3) MWF_AGE (83h): Birth date and age

This tag is to encode the birth date and age (Table 54). The age is based on the date of examination or measurement.

Table 54 — Birth date and age

MWF_AGE				Data length	Default	Remarks	Duplicated definitions
131	83h	Age	Years	1	None	—	Override
			Days	2			
		Date of birth	Year	2			
			Month	1			
			Day	1			

4) MWF_SEX (84h): Gender

This tag is to encode the sex of the patient (Table 55), using the codes shown in Table 56.

Table 55 — Gender

MWF_SEX		Data length	Default	Remarks	Duplicated definitions
132	84h	1	Unclear	—	Override

Table 56 — Gender code

Sex	Value
Unclear	0
Male	1
Female	2
Undefined	3

5) MWF_TIM (85h): Measurement date/time

This tag is to encode the examination/measurement date/time or the data acquisition date/time (Table 57). The date/time has an important meaning in encoding storage objects with MFER so it should be used carefully.

Table 57 — Measurement time

MWF_TIM			Data length	Default	Remarks	Duplicated definitions
133	85h	Year	2	None	1 900 to 2 100	Override
		Month	1		1 to 12	
		Day	1		1 to 31 (1 to 30, 1 to 28, 29)	
		Hour	1		0 to 23	
		Minute	1		0 to 59	
		Second	1		0 to 59	
		Millisecond	2		0 to 999	
		Microsecond	2		0 to 999	

6) MWF_MSS (86h): Message

This tag is to encode a character string of an interchangeable message between systems (Table 58).

Table 58 — Message

MWF_MSS		Data length	Default	Remarks	Duplicated definitions
134	86h	Str ≤ 1024	none	Message will be defined for each purpose	Duplicated definition possible

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Annex A

(informative)

MFER conformance statement

Each implementer should provide a specification sheet of their specific MFER waveform format as a conformance statement (Table A.1). Use of non-default values should be identified clearly. If the extension part of the MFER description is used, an additional sheet with other optional extensions should also be provided.

Table A.1 — Conformance statement template

MFER specification						Frame		/		Ver.		
Producer	Manufacturer					Date				Model		
	Author					Edited date						
Waveform title							Specification					
Preamble						Endianity		•Default(big endian) •Big endian •Little endian				
Version	..		Character									
Sampling attributes	Sampling rate		Unit				Exponent				Mantissa	
	Sampling resolution		Unit				Exponent				Mantissa	
Data type	•Default •()			NULL		•Not used •()			Offset value		•Not used •()	
Frame number			Block				Channel				Sequence	
Channel No.	Lead or Waveform		Condition							Remarks		
Note												

Annex B (informative)

Description example

B.1 Data alignment example

B.1.1 Alternate mode format

The frame is composed of a single sequence of consecutive data blocks where all data values of a channel (lead) are encoded.

With example shown in Figure B.1, the entire lead I ECG is assigned to one data block and leads II to aVF are sequentially assigned to subsequent data blocks to form the first frame. In the same way, leads V1 to V6 are assigned to sequential data blocks to form the second frame.

- Data block length: All data values of one lead; e.g. 5 s
- Number of channels: 6
- Number of sequences: 1
- Number of frames: 2

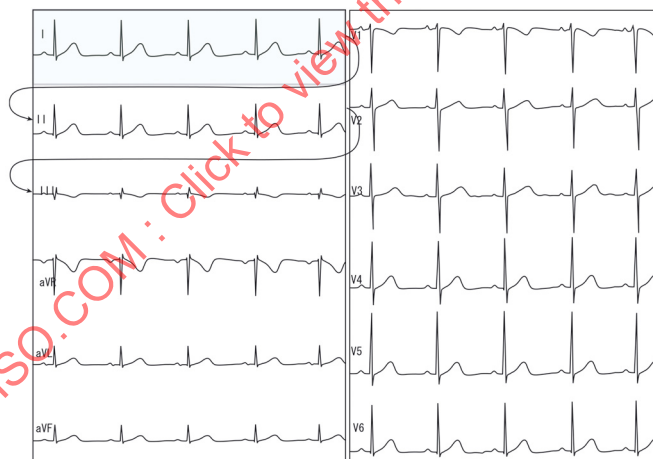


Figure B.1 — Alternate mode description

B.1.2 Multiplex mode format

The frame is composed of a number of sequences where each sequence consists of a short data block for each consecutive channel. The data block contains the data values for a short segment of the waveform of a channel shown in Figure B.2.

- Data block length: one sampled data
- Number of channels: 6
- Number of sequences: Number of data blocks in one channel; e.g. 5-second ECG per lead
- Number of frames: 2

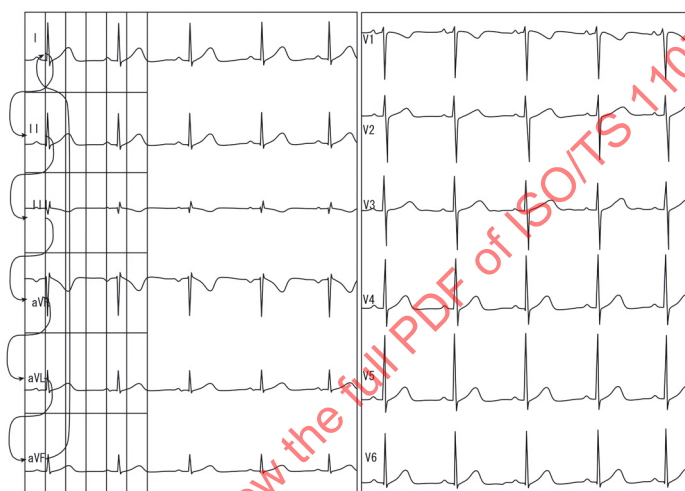


Figure B.2 — Multiplex mode

B.2 Description format

MFER encodes waveform data values in frames which include a header to identify the contents. The header describes sampling conditions, frame alignment and other related information. The information for the header should be encoded with the TLV (tag, length and value) conforming to the encoding rules (Figure B.3). Descriptors include the root definition which covers all encodings and channel definitions which cover encodings for relevant channels.

EXAMPLE Alignment of waveform data values.

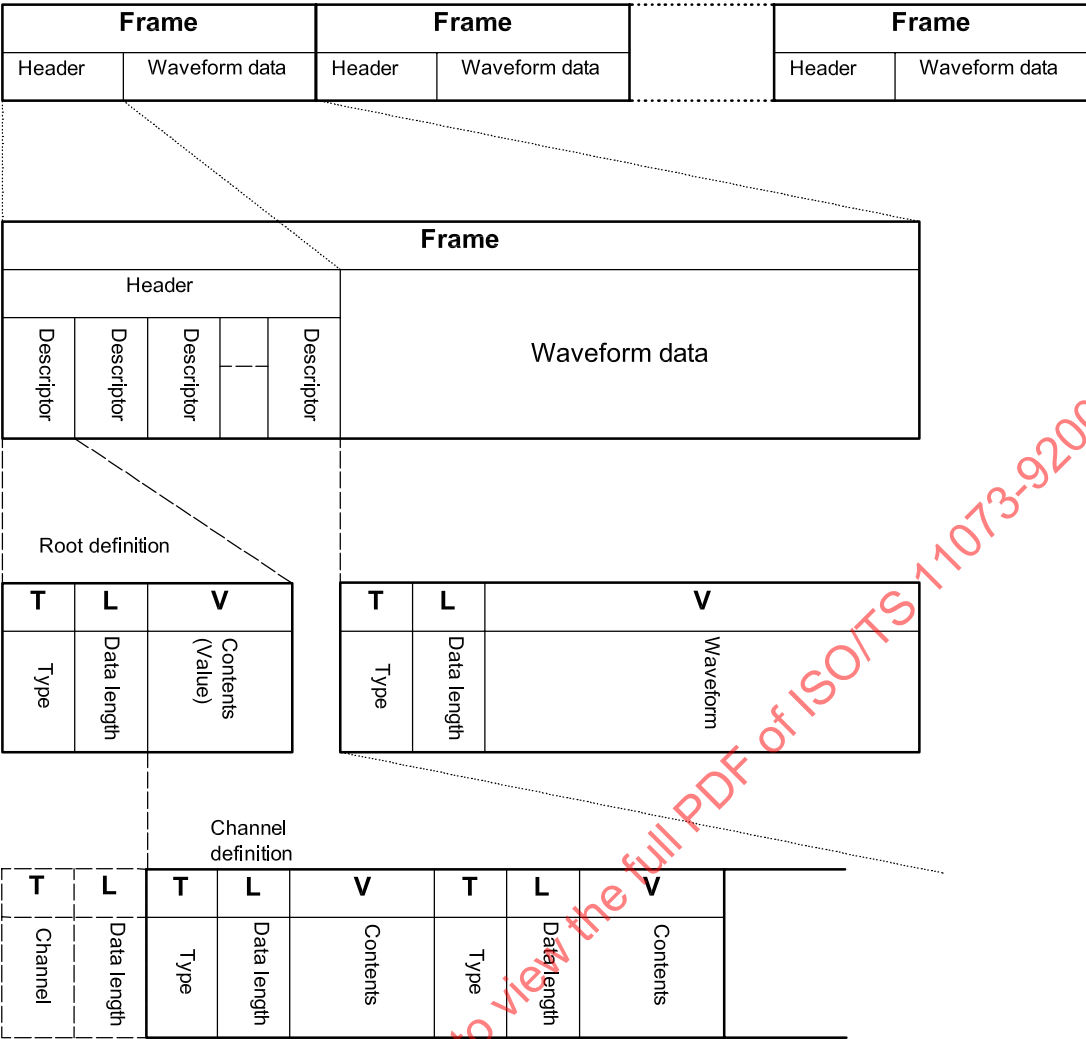


Figure B.3 — Encoding format

Figure B.4 shows an alignment of data values in a frame. One data block consists of five sampled data. If each value is encoded with a 16-bit integer, one data block is formed with 10 octets. As the number of channels is three, three data blocks, each consisting of five sampled data, are encoded in one data group through one sequence. The sequence is repeated four times in this example.

If sampling is made at 4 ms intervals, that is at a frequency of 250 Hz, 20 ms data (4 ms × 5 sampled data = 20 ms) are stored in one block. As the number of sequences is 4, the waveform data per each channel is 80 ms (20 ms × 4) in length.

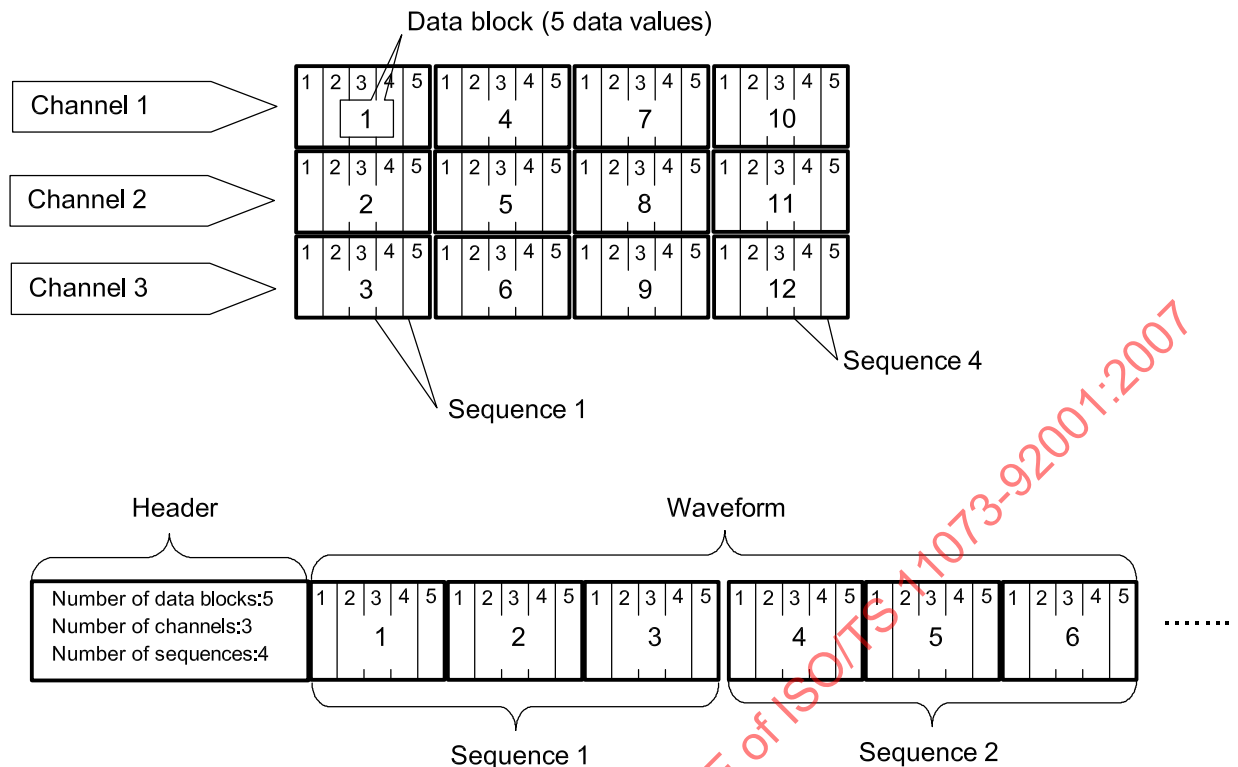


Figure B.4 — Waveform data alignment

B.3 Waveform time and synchronization

B.3.1 General

The acquisition time of the waveform is not available unless it is specified by a supplementary definition. The time, if defined with MFER, is indicated by an offset time (MWF_PNT) from an external reference clock. Thus, the time depends on the system clock. If the system manages the clock as an absolute clock, the time of waveform is an absolute time. If the time is uniformly managed with a clock within the system, the time of the waveform follows the system clock. If the time is managed within an instrument such as an electrocardiograph, the time of the waveform depends on the originating instrument.

a) Reference clock

If the reference clock is managed under the absolute time of GPS or the like, MFER describes the time of the waveform with an absolute time. Accordingly, synchronized processing is possible between different systems if they are managed under an absolute clock. If a reference clock is managed within a system, synchronized processing is possible within the system. If a clock is managed within an instrument, synchronized processing is possible within the instrument.

b) Pointer

A pointer value (see Figure B.5) is managed by the sampling time interval defined in the root definition. If a sampling interval is different between frames, the reference differs frame by frame. As the root sampling interval is 1 ms and a pointer is represented in signed 32 bits, it can represent up to 24,8 days as a time offset.

c) Synchronization

The value of an event such as beat annotation is represented with the time (number of sampling times) indicated by the sampling interval defined in the root or channel definition.

d) Renewal of pointer

If two or more frames are used, the pointer advances by the number of data values at the end of each frame. If the pointer for a subsequent frame is set to default, the frame succeeds to the pointer of the previous frame. For example, if the pointer is zero at the start of the previous frame and 5 s data (5 000 data values with a sampling interval of 1 ms) are encoded in the frame, the pointer is renewed to 5 000 at the end of the frame and the subsequent frame uses the pointer set at 5 000. Accordingly, if the pointer is not controlled at each frame, these waveform data are encoded as continuous frames.

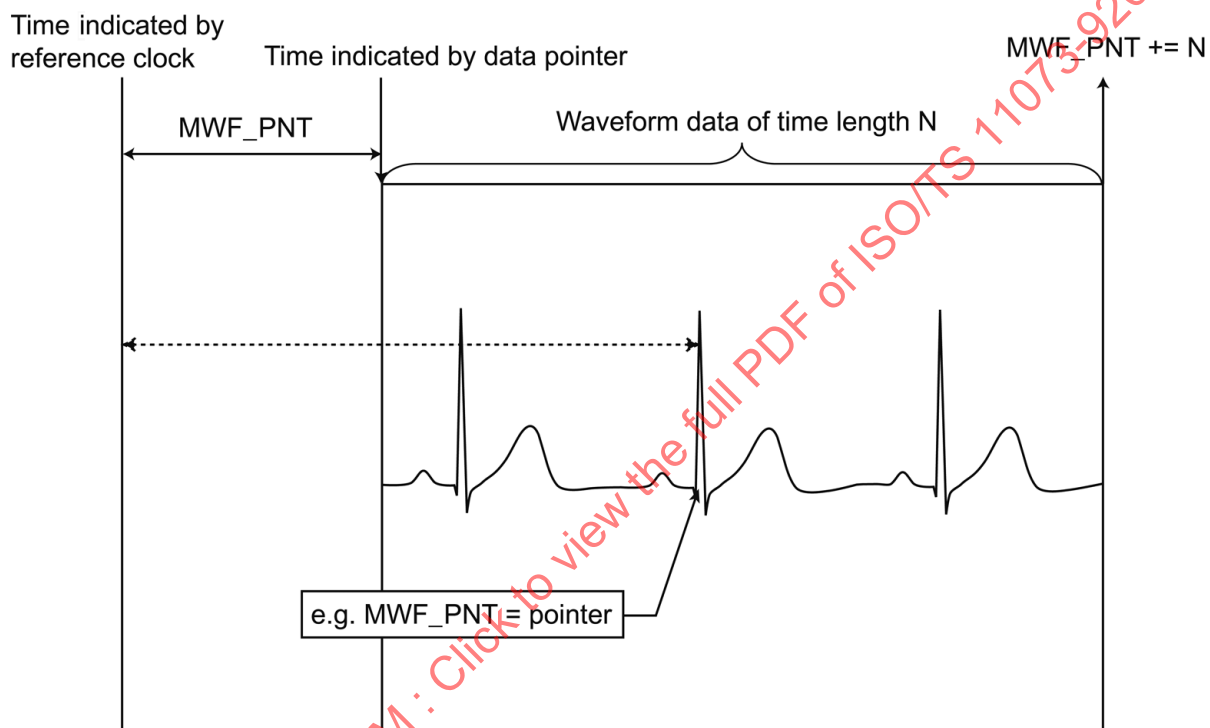


Figure B.5 — Pointer and timing

e) Pointer management

- For a long duration data acquisition system such as a patient monitoring system, the A/D converter clock may differ from the master clock. In such a case, the pointer of subsequent frames can manage skipped (leap data) or defective data.
- In stored data or received data, the pointers indicate whether each frame is continuous or not.

B.3.2 Frame encoding examples

B.3.2.1 In case the number of data values is less than the frame encoding

Suppose block length is 5, the number of channels is 3 and the number of sequences is 4. If the total number of real data values is $(5 \times 3 \times 3 + 8)$, seven remaining data value fields are processed as no data (Figure B.6).