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Health informatics — Medical waveform format

Part 2: Electrocardiography

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Health informatics — Medical waveform format —

Part 2: Electrocardiography

Informatique de santé — Forme d'onde médicale —

Partie 2: Electrocardiographie

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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*.

ISO/TS 22077 consists of the following parts, under the general title *Health informatics — Medical waveform format*:

— *Part 1: Encoding rules*

— *Part 2: Electrocardiography*

— *Part 3: Long term electrocardiography*

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Introduction

The standard 12-lead electrocardiogram (ECG) is one of the most widely used medical waveforms in clinical sites. In particular, the increased usage of electronic medical records provides the environment in which these ECGs can be accurately utilized; however, it is essential that to address the therapeutic requirements, ECG use is not constrained to specific machine types and manufacturers. Furthermore, there is great interest in the various kinds of patient information contained in ECGs that are extensively studied and shared between health care providers.

This Technical Specification defines the detailed rules for electrocardiogram waveform format that is encoded according to the medical waveform format encoding rules (MFER). In addition to electrocardiogram waveform format encoding, there are rules for other waveforms such as long-term ECG (Holter ECG), stress ECG, etc. that are contained in other MFER technical specifications. Please refer to those specifications for additional information.

About MFER

Medical waveforms such as electrocardiogram, electroencephalogram, and blood pressure waveforms are widely utilized in clinical areas such as physiological examinations, electronic medical records, medical investigations, research, education, etc. Medical waveforms are used in various combinations and document types according to the intended diagnostic purpose. For example, ECG waveforms are utilized extensively in the clinical arena, with resting 12-lead ECG being used the most. A cardiologist makes diagnoses using 10 s to 15 s ECG waveform measurements; however, longer periods are sometimes required to recognize patient heart conditions such as arrhythmia. Also, there are many other methods using ECG such as Holter ECG, physiologic monitoring ECG, stress ECG, intracardiac ECG, VCG, EEG with ECG, blood pressure with ECG, PSG, etc. MFER can describe not only ECG for physiological examinations conducted in ICU and operating room acute care contexts, but also EEG, respiration waveform, and pulse.

Simple and easy

MFER is a specialized representation for medical waveforms that removes unnecessary coded elements (“tags”) for waveform description. For example, a standard 12-lead ECG can be described simply only using a common sampling condition and the lead condition, making waveform synchronization and correct lead calculation much easier.

Using with other appropriate standards

It is recommended that MFER only describes medical waveforms. Other information can be described using appropriate standards such as HL7, DICOM, IEEE, etc. For example, clinical reports that include patient demographics, order information, medication, etc. are supported in other standards such as HL7 Clinical Document Architecture (CDA); by including references to MFER information in these documents, implementation for message exchange, networking, database management that includes waveform information becomes simple and easy.

Separation between supplier and consumer of medical waveforms

The MFER specification concentrates on data format instead of paper-based recording. For example, recorded ECG is processed by filter, data alignment, and other parameters, so that the ECG waveform can be easily displayed using an application viewer. However, it is not as useful for other purposes such as data processing for research investigations. A design goal of MFER is that a waveform is described in raw format with as complete as possible recording detail. When the waveform is used, appropriate processing of the data are supported like filtering, view alignment and so on. In this way, the medical waveform described in MFER can be used for multiple purposes.

Product capabilities are not limited

Standards often support only a minimum set of requirements, so the expansion of product features can be greatly limited. MFER can describe medical waveform information without constraining the potential features of a product. Also, medical waveform display must be very flexible, and thus MFER

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has mechanisms supporting not only a machine-readable coded system for abstract data, but also human-readable representation.

The MFER specification can support both present and future product implementations. MFER supports the translation of stored waveform data that was encoded using other standards, enabling harmonization and interoperability. This capability supports not only existing waveform format standards, but can be extended to support future formats as well.

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Health informatics — Medical waveform format —

Part 2: Electrocardiography

1 Scope

This Technical Specification defines the application of medical waveform format encoding rules (MFER) to describe standard electrocardiogram waveforms measured in physiological laboratories, hospital wards, clinics, and primary care medical checkups. It covers electrocardiograms such as 12-lead, 15-lead, 18-lead, Cabrera lead, Nehb lead, Frank lead, XYZ lead, and exercise tests that are measured by inspection equipment such as electrocardiographs and patient monitors that are compatible with MFER.

Medical waveforms that are not in the scope of this Technical Specification include Holter ECG, exercise stress ECG, and real-time ECG waveform encoding used for physiological monitors.

2 Normative references

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

ISO 22077-1, *Health informatics — Medical waveform format — Part 1: Encoding rules*

3 Terms and definitions

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

3.1
dominant beat
typical heart beat used for measurement and analysis in standard 12-lead ECG

Note 1 to entry: In general, it is the primary heart beat excepting extrasystole or drifts of baseline.

3.2
average beat
typical heart beat used for measurement and analysis in standard 12-lead ECG

Note 1 to entry: This is averaged for waveforms excluding abnormal beats for each lead.

3.3
median beat
typical heart beat used for measurement and analysis in standard 12-lead ECG

Note 1 to entry: This is a waveform with the median value of waveforms excluding the abnormal beats for each lead.

3.4
tag
identifier code for a semantic concept

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4 Symbols and abbreviated terms

CEN	Comité Européen de Normalization/European Committee for Standardization
DBMS	Data Base Management system
DICOM	Digital Imaging and Communications in Medicine
ECG	Electrocardiogram
EEG	Electroencephalogram
EHR	Electronic Health Record
GPS	Global Positioning System
HL7	Health Level Seven
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
JIS	Japanese Industrial Standard
LSB	Least significant bit
MFER	Medical waveform Format Encoding Rules
MSB	Most significant bit
OID	Reference to the ISO standard
SAS	Sleep Apnea Syndrome
SCP-ECG	Standard Communications Protocol for Computerized Electrocardiography (ISO IS 11073-91064)
SpO2	Saturation of Peripheral Oxygen
UID	Reference to the ISO standard
UUID	Reference to the ISO standard
VCG	Vectorcardiogram
XML	Extensible Markup Language

5 Encoding format

5.1 Primary description

MFER provides encoding of Long-term ECG waveforms but since MFER is used mutatis mutandis for encoding of ECG waveforms such as ambulatory ECG, patient monitor system, etc., In addition, together with encoding of ECG waveforms, encoding of information of recognition for waveform, measurement information, interpretation information, etc. is provided, but these are all optional functions and are dependent on each implementation concept. For instance, interpretation code or measurement value might be described by other standard such as HL7, XML, DBMS, etc. with waveforms decoding MFER. However, in all instances, when implementing a device, apply the requirements as listed in ISO 22077-1.

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5.1.1 Sampling attributes

Sampling attributes including sampling rate and resolution are given in Tables 1 to 4.

5.1.1.1 MWF_IVL (0Bh): Sampling rate

This tag indicates the frequency or sampling interval for the medical waveform is sampled (Table 1).

Table 1 — Sampling rate

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

The unit may be frequency in hertz, time in seconds, or distance in meters (Table 2).

Table 2 — Sampling rate unit

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

5.1.1.2 MWF_SEN (0Ch): Sampling resolution

This tag indicates the resolution, minimum bits, the medical waveform sampled (generally, digitized) (Table 3).

Table 3 — Sampling resolution

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

Table 4 — Sampling units

Unit		Value	Default	Remarks
Voltage	Volt	0	0,000 001 V	—

5.1.2 Frame attributes

A frame is composed of data blocks, channels and sequences.

5.1.2.1 MWF_BLK (04h): Data block length

This tag indicates the number of data sampled in a block (Table 5).

Table 5 — Data block length

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

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5.1.2.2 MWF_CHN (05h): Number of channels

This tag indicates the number of ECG channels (Table 6). If a 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 within the definition of a channel attribute.

Table 6 — Number of channels

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

5.1.2.3 MWF_SEQ (06h): Number of sequences

This tag indicates the number of sequences (Table 7). 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 that are defined for the specified frame.

Table 7 — Number if sequences

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

5.1.3 Waveform

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

5.1.3.1 MWF_WFM (08h): Waveform class

Waveforms such as standard 12-lead ECG and monitoring ECG are grouped based on instruments and purpose, as shown in Table 8.

Table 8 — 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, each type of waveform is described in a separate specification.

For types of waveforms (Table 9), numbers 1 to 49151 (BFFFh) are reserved. Numbers 49152 to 65535 can be used privately, but it is recommended to add these to the MFER specification rather than rely on private extensions.

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Table 9 — Standard 12-lead ECG waveforms

Waveform kind	Type	Value	Waveform description	Remarks
Electrocardiogram	ECG_STD12	1	Standard 12-lead ECG	Standard 12-lead ECG including general ECG in short-term recording.
	ECG_BEAT	9	QRS beat	In general, one heart beat waveform extracted from standard 12-lead ECG recording. Write comment Average, Median, Dominant
	ECG_DRV	12	Derived lead	Derived ECG from Frank vector leads, EASI lead, etc.

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

This is the waveform code used in 12-lead ECGs and vector lead ECGs. Because the lead code is encoded by 0 to 127, care should be taken when other standards such as SCP-ECG, etc. are followed. Since part of these code spaces overlap, the present table shall be followed in all MFER applications.

Since in this specification, the code for the lead name is encoded by 127 or less, the codes specified in systems such as SCP-ECG shall require conversion. However, in the present lead code table, leads which are not used in standard 12-lead ECG are defined and, in general, will not need to be replaced.

Table 10 — Definition of waveform attributes

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

The present code supports 12-lead electronic cardiogram waveforms. In this Technical Specification, it is recommended to encode leads using MFER waveform information, rather than those specified in other standards.

In addition, this Technical Specification extends the 12-lead names for humans to include ECG lead names for animals. When other leads for animals are used, such as CV5RL, CV6LL, CV6LU, and V10, they should be specified by waveform information.

Table 11 — Lead name

Code	Lead	Code	Lead
1	I	—	—
2	II	—	—
3	V1	—	—
4	V2	—	—
5	V3	—	—
6	V4	—	—
7	V5	—	—
8	V6	—	—
9	V7	—	—

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Table 11 *(continued)*

Code	Lead	Code	Lead
10	[b]	—	—
11	V3R	61	III
12	V4R	62	aVR
13	V5R	63	aVL
14	V6R	64	aVF
15	V7R	65	-aVR[a]
16	X	66	V8
17	Y	67	V9
18	Z	68	V8R
19	CC5	69	V9R
20	CM5	70	D(Nehb Dosal)
—	—	71	A(Nehb Anterior)
31	NASA	72	J(Nehb Inferior)
32	CB4	—	—
33	CB5	—	—
34	CB6	—	—

[a] aVR lead shall not be encoded according to MFER. The users (viewer) should mke a calculation to derive –aVR when required.

[b] Although V2R (10) is defined in other rules such as SCP-ECG, the definition shall not be used in MFER.

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 Annex D for the definition of waveform attributes.

As the lead names are defined depending on the class of waveform, the lead subsets are not called out for 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 can be used privately but it is recommended to add these to the MFER specification rather than rely on private extensions.

5.1.3.3 MWF_WAV (1Eh): Waveform data

The entire set of waveform data should be strictly aligned as defined in Frame attributes. If the waveform data are compressed, the data alignment may depend on the compression method, but the waveform data after un-compressing should be aligned according to the definition. Refer to Annex B.

If waveform data are different from what is defined in frame information, they may be discarded depending on application processing. MFER behaviour is undefined in this case.

5.1.4 Channel

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

This tag defines the attributes for each channel (see Table 12). Before this definition, the channel number shall be specified using the values in Table 6.

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Table 12 — 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.

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

8	7	6	5	4	3	2	1		
0	0	1	31(1Fh)					0	Channel number
		63(3Fh)							

Figure 1 — Number of channel

The data length includes all the range of the channel attribute definition (Figure 2).

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

Figure 2 — Definition of channel attributes

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

Figure 3 — Definition of channel attributes with indefinite length

5.2 Data alignment

This Technical Specification supports many ECG alignment styles according to Annex B, allowing for complicated alignment formats that could result in processing issues. It is recommended that formats be simplified as much as possible in order to maximize interoperability.

5.3 Abstract waveform

This example is in principle the same as the 12-lead ECG, but one heartbeat of P-QRS-T is extracted and expressed. The abstract waveform is processed in three ways: extraction as dominant beat, averaged beat and median beat. These depend on the system concept and measurement method. The abstract waveform should be clearly stipulated in implementation specifications, but all leads may be encoded by abstract waveform of MFER.

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