TECHNICAL SPECIFICATION

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Health informatics — Medical waveform format —

Part 3: Long term electrocardiography

Informatique de santé — Forme d'onde médicale —

Partie 3: Électrocardiographie de longue durée

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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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*

Introduction

The ambulatory ECG examination is widely utilized in the clinical field. This rule applies for long-term waveform description such as ambulatory ECG, monitoring waveforms, etc. Recently, EMR, or Electronic Medical Records, becomes commonly used and it strongly requires Ambulatory ECG examination for the therapeutic purpose. However, new digitalized data of Ambulatory ECG recorder cannot be used among different manufacturers scanner. This Technical Specification intends that MFER encoded data for ambulatory ECG is analysed by other scanner and these are also interoperable on EMRs.

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

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.

Health informatics — Medical waveform format —

Part 3: Long term electrocardiography

1 Scope

This Technical Specification defines the application of medical waveform format encoding rules (MFER) to describe long-term electrocardiogram waveforms measured in physiological laboratories and health care clinics. It covers electrocardiograms such as bipolar 2, 3-lead, 12-lead that are measured by medical equipment such as Holter electrocardiograph and patient physiological monitors that are compatible with the medical waveform format Encoding rules (MFER) Technical Specification (ISO 22077-1).

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, *Medical waveform format — Part 1: Encoding rules*

3 Terms and definitions

3.1
recorder
recording equipment worn or carried by the patient including associated electrodes and cables for recording or recording and analysing heart action potentials

Note 1 to entry: Some recorders can record not only ECG but also non-invasive blood pressure measured automatically, SpO2, and respiratory waveform.

3.2
scanner
equipment that retrieves ECG waveforms from the recorder and analyses and edits ECG waveforms provided by the recorder to determine the presence of abnormal heart rhythms such as arrhythmia

3.3
patient event
information or event for analysing the ECG.

EXAMPLE For example, they may have chest pain, dizziness, or palpitatins, etc. Pushing a “patient event” switch located on the recorder allows for recording ECG waveforms with the time of occurrence.

3.4
heart beat
ECG cycle, comprising the P,QRS and the ST-T wave

3.5
dominant beat
typical heart beat used for measurement and analysis

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

3.6
average beat
typical heart beat used for measurement and analysis

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

3.7
abstract waveform
one heartbeat of P-QRS-T, extracted by each lead for analyzing and editing

3.8
low battery
<information>battery voltage is low and exchange of battery is required

3.9
leads off
<information> electrodes are disconnected

3.10
out of range
<information in patient monitoring system>poor condition on the radio field

3.11
pacing pulse
pulsed waveform from artificial pacemaker

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.

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	Sampling rate 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 of least significant bit for ECG waveform sampled (generally, digitized) (Table 3).

Table 3 — Sampling resolution

MWF_SEN			Data length	Default	Encoding range/remarks	Duplicated definitions
12	0Ch	Sampling resolution unit	1	See Table 6	—	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

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 attributes 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 class

Long-term ECG waveform is grouped based on instruments and purpose, as shown in Table 8.

Table 8 — Waveform class

MWF_WFM		Date length	Remarks	Duplicated definitions
08	08h	2		Override
		Str ≤ 32	Waveform encoding	

As a general rule, each type of waveform is described in a separate specification.

For types of waveforms (Tables 9 to 10), 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.

Table 9 — Long-term ECG waveform-1

Major classification	Type	Value	Waveform descriptions	Remarks
Electrocardiogram	ECG_LTERM	2	Long-term ECG	Ambulatory ECG Patient monitoring system ECG

a) It is recommended that ECG classified into the type ECG_LTERM is used when it takes over 30 min for measurement, because application system such as viewer may have different display format for each waveform type. However, this recommendation is not a requirement.

b) In addition, extracted waveforms which are used in the long-term ECG are shown in Table 10. These waveforms shall be extracted after being analysed and edited, and then shall be used for scanning.

Table 10 — Long-term ECG waveform-2

Major classification	Type	Value	Waveform descriptions	Remarks
Electrocardiogram	ECG_BEAT	9	Dominant beat extracted waveform	Extracted waveform for one beat by ambulatory ECG Write comment Average, Median, Dominant

5.2 Data alignment

Data alignment recommended by ambulatory ECG standard shall be prescribed. Data alignment should be simple as much as possible in order to prevent troubles caused by the complication which may result in some limitation of interoperability by using complicated format.

5.2.1 Data encoding

In long-term ECGs, the recorder for recording ECG waveforms, the scanner for analysing and editing ECG waveforms, and the electronic medical record for referring waveforms shall be encoded in the most appropriate format respectively in accordance with MFER.

— Recorder encoding: The recorder encodes ECG waveforms on the assumption that it processes the data in real time. The data encoded by the recorder shall be regarded as the original data (original ECG). This encoding format is defined in view of the risk of sudden disconnection of battery or other record media in patient's daily life. Furthermore, encoding of information including pacemaker spike and patient event shall be also prescribed.

— Scanner encoding: In the scanner encoding, information derived from analysing and editing the long-term ECG data recorded by the recorder shall be added to the original data. This encoding format is defined in view of reading MFER file with the scanner, and the secondary information, including heart beat code or event strip created by the scanner, shall be encoded in this format. This format also shall be used to output data from the scanner to the host system such as electronic medical record in accordance with MFER.

5.2.2 Recorder encoding

In recorder encoding, the following points should be noted:

— In view of sudden disconnection of battery or other record media, the data recorded by the time of the disconnection should be kept to allow for reading data in a proper format.

— Information on patient event or body movement should be in the same way as ECG and respiratory waveforms, so that every user can read data without any difficulty.

5.2.2.1 Encoding of waveforms

In recorder encoding, waveforms shall be encoded according to MWF_WAV (1Eh), and shall consist of lead, status and stopper. Figure 1 shows one minute waveform data, and it is an example of waveform data recorded using leads called CM5 and NASA.

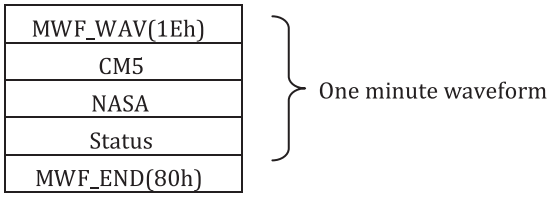

Figure 1 — Encoding of waveform

MWF_END (80h) tag shall be encoded at the end of the file as a stopper.

In encoding waveforms, it is practical to use a multiple frame.

It is practical to use multiple frames to encode waveforms. Frames are usually created in the order that waveforms are generated, and then the frames shall be aligned to create waveforms.

Frame 1		Frame 2		Frame 3
Header -1	Wave body	Header -2	Wave body	Header-3

Figure 2 — Multiple frame configurations

In encoding successive waveforms with the multiple frames, waveforms encoded with frames later than Frame 2 are usually the same with pre-encoded condition or status in Frame 1. For example, the sampling frequency and waveform code are usually the same. In such case, according to MFER, the header is frequently omissible.

5.2.2.2 Encoding format for pacemaker spike and patient event

Pacemaker spike and patient event shall be encoded by data type MWF_DTP (0Ah) “16-bit status”.

Table 11 — Waveform information (status)

MWF_DTP		Data length	Default	Remarks	Duplicated definitions
10	0Ah	1	N.A.		Override

Table 12 — Definition of data type

Value	Data type
4	16-bit status

Pacemaker information shall be encoded with 16-bit status.

