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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
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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

This first edition of ISO 22077-3 cancels and replaces ISO/TS 22077-3:2015, which has been technically revised.

The main changes are as follows:

— Clause 3 has been updated;

— editorial corrections.

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

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

Introduction

The long-term electrocardiography (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, became commonly used and it strongly requires long-term ECG examination for the therapeutic purpose. However, new digitalized data of long-term ECG recorder cannot be used among different manufacturers scanner. This document intends that MFER encoded data for long-term ECG is analysed by other scanner and these are also interoperable on EMRs.

This document defines the detailed rules for electrocardiography waveform format that is encoded according to the medical waveform format encoding rules (MFER). In addition to electrocardiography waveform format encoding, there are rules for other waveforms such as standard 12-lead ECG, stress ECG, etc. that are contained in other MFER documents.

About MFER

Medical waveforms such as ECG, electroencephalography (EEG), 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, vectorcardiography (VCG), EEG with ECG, blood pressure with ECG, sleep polysomnography (PSG), etc. MFER can describe not only ECG for physiological examinations conducted in intensive care unit (ICU) and operating room acute care contexts, but also EEG, respiration waveform, and pulse.

— **Implementation:** 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.

— **Use with other appropriate standards:** it is recommended that MFER only describes medical waveforms. Other information can be described using appropriate standards published by organization including HL7®[1)], DICOM®[2)], and IEEE®[3)], 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, the ECG recordings displayed as images are 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 is supported such as filtering, view alignment, etc. In this way, the medical waveform described in MFER can be used for multiple purposes.

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2) DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

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— **Product capabilities are not limited:** standards often support only a 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 supports 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 document defines the application of medical waveform format encoding rules (MFER) to describe long-term electrocardiography waveforms measured in physiological laboratories and health care clinics. It covers electrocardiography 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 MFER documents encoding rules (see ISO 22077-1).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22077-1 and the following apply.

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

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

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

3.1.1
recorder
equipment worn or carried by the patient with the intention of recording and analysing heart action potentials

3.1.2
scanner
equipment that retrieves ECG waveforms from the heart recorder and analyses, edits the information received to determine the presence of abnormal heart rhythms and reports

3.1.3
patient ECG recording event
manual marking of clinical information during ECG recording

Note 1 to entry: There shall be a “patient ECG recording event” switch on the recorder. It can be pushed to mark and timestamp a clinical event affecting the assessment of the ECG waveform. For example, the patient can have chest pain, dizziness or palpitation. Pushing a “patient ECG recording event” switch located on the recorder allows for recording ECG waveforms with the time of occurrence.

3.1.4
dominant beat
primary heart beat extracted from typical beats for each lead in a period of long-term ECG

Note 1 to entry: The dominant beat is used for measurement and analysis of ECG in the period and easily viewing the change of ECGs for each period.

Note 2 to entry: In general, it is the typical heart beat excepting extrasystole or drifts of baseline.

3.1.5
average beat
beat waveform constructed from the average value of each temporal point in ECG across a number of beats

3.1.6
median beat
beat waveform constructed from the median value of each temporal point in ECG across a number of beats

3.1.7
leads off
disconnected electrodes

3.2 Abbreviated terms

CDA	Clinical Document Architecture
DBMS	Data Base Management system
DICOM	Digital Imaging and Communication in Medicine
ECG	Electrocardiography
EEG	Electroencephalography
EMR	Electronic Medical Record
HL7	Health Level Seven
ICU	Intensive Care Unit
IEEE	Institute of Electrical and Electronic Engineers
MFER	Medical waveform Format Encoding Rules
NIBP	Non-Invasive Blood Pressure
PSG	Sleep Polysomnography
SCP-ECG	Standard communication protocol — Computer-assisted electrocardiography (ISO 41064)
SpO_2	Saturation of Peripheral Oxygen
VCG	Vectorcardiography
XML	Extensible Markup Language

4 Encoding format

4.1 Primary description

4.1.1 General

This document provides the encoding of long-term ECG waveforms. It also supports encoding other ECG waveforms such as ambulatory ECG and real-time physiological monitoring. In addition, along with the ECG waveform encoding, the encoding of waveform recognition information, measurement information, interpretation information, etc. is provided, but these are all optional functions and depend on each implementation concept. For instance, interpretation codes or measurement values are described by other standard including HL7 CDA, XML, and DBMS, etc. with waveforms decoding MFER. However, in all instances, when implementing a device, apply the requirements as listed in ISO 22077-1.

In order to make effective use of this document, a MFER conformance statement is provided in Annex A and sample waveform description are provided in Annex C.

4.1.2 Sampling attributes

4.1.2.1 General

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

4.1.2.2 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		$10^{-128 \text{ to } +127}$	
		Mantissa	≤ 4		e.g. unsigned 16-bit integer	

The unit can 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	—

4.1.2.3 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 4	—	Override
		Exponent (10th power)	1		$_{10}$ -128 to +127	
		Mantissa	≤ 4		e.g. unsigned 16-bit integer	

Table 4 — Sampling units

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

4.1.3 Frame attributes

4.1.3.1 General

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

4.1.3.2 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

4.1.3.3 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

4.1.3.4 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

4.1.4 Waveform class

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

Table 8 — Waveform class

MWF_WFM		Data 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 and 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
Electrocardiography	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 can have different display format for each waveform type.

b) In addition, extracted waveforms that 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
Electrocardiography	ECG_BEAT	9	QRS waveform	Extracted waveform for one beat by long-term ECG Write comment Average, Median, Dominant beat

4.2 Data alignment

4.2.1 General

Data alignment recommended by long-term ECG standard shall be specified. Data alignment should be as simple as possible in order to prevent troubles caused by the complication which can result in some limitation of interoperability by using complicated format.

4.2.2 Data encoding

In long-term ECGs, the recorder for recording ECG waveforms, the scanner for analysing and editing ECG waveforms, and the EMR for referring waveforms shall be encoded in the most appropriate format 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 specified.

— 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.

4.2.3 Recorder encoding

4.2.3.1 General

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 in order to read 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.

4.2.3.2 Encoding of waveforms

In recorder encoding, waveforms shall be encoded in accordance with 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. CM5 and NASA are part of the lead shown in Tables 21, D.1, and D.2.Examples of status are shown in Table 22.

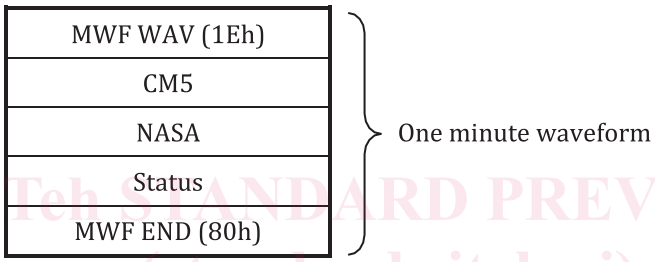

Figure 1 — Encoding of waveform

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

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

Figure 2 shows the structure of multiple frame configurations.

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 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.

4.2.3.3 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”, as shown in Tables 11 and 12.