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Health informatics — Medical waveform format —

Part 5: Neurophysiological signals

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Foreword

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

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

Neurophysiological signals are used to monitor and assess an individual's brain activity for a wide array of clinical examinations including sleep polysomnography (PSG), determination of brain death, evoked potentials (EP), and electromyography (EMG).

Electroencephalography (EEG) is an electrophysiological monitoring method to record electrical activity of the brain. It is typically non-invasive, with multiple electrodes placed along the scalp (see Figures B.1 and B.2). Diagnostic applications generally focus on the spectral content of EEG, that is, the type of neural oscillations (popularly called "brain waves") that can be observed in EEG signals. EEG is most often used to diagnose epilepsy, which causes abnormalities in EEG readings. It is also used to diagnose sleep disorders, coma, encephalopathies, and brain death.

PSG examinations include monitoring the condition of the body during sleep at night. Confirmed diagnosis of sleeping disorders and sleeping respiratory disorders is supported by recording neurophysiological signals through electrodes. By measuring brain waves, eye movements, electromyogram movements, etc., the depth of sleep (sleep stage), quality, presence or absence of midwake arousal, respiration by breathing, snoring, oxygen saturation, etc., can be assessed.

To correctly interpret neurophysiological changes, medical device systems need to capture these data, along with additional waveforms such as the respiration, SpO2, EOG (eye movement). Healthcare providers and clinical specialists who perform these examinations greatly benefit from interoperability – having all the examination data recorded in a single standardized package or file that can be safely and securely managed and exchanged.

The purpose of this document is to describe the heterogeneous neurophysiological waveforms and related data that can be normalized to a standard semantic representation and format and persisted in a single package. The specification also supports the time synchronization of these waveforms and related parametric data so that the clinician receiving the data package is able to better assess the patient's condition throughout the examination period.

About Medical waveform Format Encoding Rules (MFER)

The MFER standards address several challenges that are not limited to either EEG waveforms or the neurophysiological assessments that are the main subject of this document:

— **Simple and easy implementation:** application of MFER is very simple and is designed to facilitate understanding, easy installation, trouble-shooting, and low implementation cost.

— **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®[1], DICOM®[2], 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/EEG are 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

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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 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 5: Neurophysiological signals

1 Scope

This document specifies a heterogeneous format of neurophysiological waveform signals to support recording in a single persistent record package as well as interoperable exchange. The document focuses on electroencephalography (EEG) waveforms created during EEG examinations. Specific provision is made for sleep polysomnography examinations (PSG), brain death determination, evoked potentials (EP), and electromyography (EMG) studies.

This document is intended for neurophysiology.

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 22077-1:2015, *Health informatics — Medical waveform format — Part 1: Encoding rules*

ISO/TS 22077-3:2015, *Health informatics — Medical waveform format — Part 3: Long term electrocardiography*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22077-1:2015 apply.

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

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

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

4 Symbols and abbreviated terms

CO2	Carbon dioxide
DC	Direct Current
DICOM	Digital Imaging and Communication in Medicine
ECG	Electrocardiography
EEG	Electroencephalography
EMG	Electromyography
EOG	Electrooculography

EP	Evoked potentials
HPF	High-frequency pass filter
IEEE	Institute of Electrical and Electronic Engineers
LOINC®[4)]	Logical Observation Identifiers Names and Codes
LPF	Low-frequency pass filter
MFER	Medical waveform Format Encoding Rules
PSG	Polysomnography
SEP	Somatosensory evoked potential
SNOMED-CT®[5)]	Systematized Nomenclature of Medicine-Clinical Terms
SpO2	Saturation of peripheral oxygen

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5 General

5.1 Overview of the rules

All MFER content (see ISO 22077-1:2015, 4.2.2), including the file header and waveform data, should be encoded based on the encoding rules that are composed of the tag, length and value (TLV), 3-tuple as shown in Figure 1.

Figure 1 — 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.

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.

5.2 Configuration of waveform data

Medical waveform data described in accordance with the MFER is an aggregate of waveform frame data that consists of a header section (encoding detailed information about the waveform) and a waveform data section (main data of waveform). See Figure 2. The header and waveform data are encoded based on the encoding rules that are composed of TLV (Tag - Data length - Value). One MFER waveform file can include several waveforms. The content of an MFER waveform file is sequentially interpreted from the beginning of the file, and a single file can contain multiple waveform definitions. Given the sequential

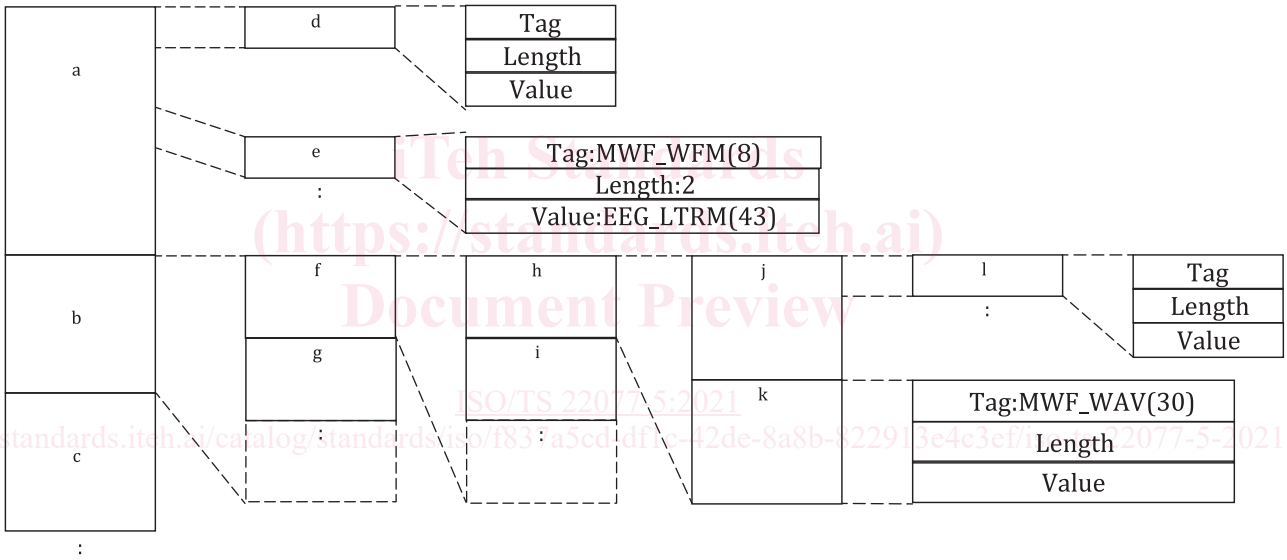
precedence processing for an MFER file, a waveform definition applies until another definition with the same tag is encountered. In this case, the subsequent definition replaces the preceding definition for the same waveform.

Additionally, the definition for one waveform can be used, by reference, to define additional waveforms in the MFER file. For example, a 60 channel EEG might only require four core waveform specifications, with the other channels referring to the same definition, providing simplification of the overall file complexity.

When there are several waveforms in a MFER waveform file, each waveform can be located anywhere in the file; however, in the specification of data generated during EEG and other examinations, waveform frames should be located as shown in Figure 2 to enhance usability and avoid erroneous interpretation:

— The information about EEG examination and others should be described before description of waveform [i.e. in (a) and (d) content should be included before (e)]. For this document, the waveform class definition(s) (MWF_WFM) are for neurophysiological signals and should be set to one of the appropriate values defined in Table 2.

— The same type waveforms should be described in a sequential, contiguous manner, and located chronologically in the file.



Key

a EEG examination
b waveform (type #1)
c waveform (type #2)
d Explanation about neurophysiological signals
e explanation (waveform class)
f waveform #1 of type #1
g waveform #2 of type #1
h frame #1 of waveform #1
i frame #2 of waveform #1
j header
k waveform data
l explanation about frame

Figure 2 — Waveform data configuration

5.3 Time synchronization

In EEG examination data, several types of neurophysiological signals and biomedical data, such as SpO2 or respiration may be described together in the same MFER file, requiring support for time

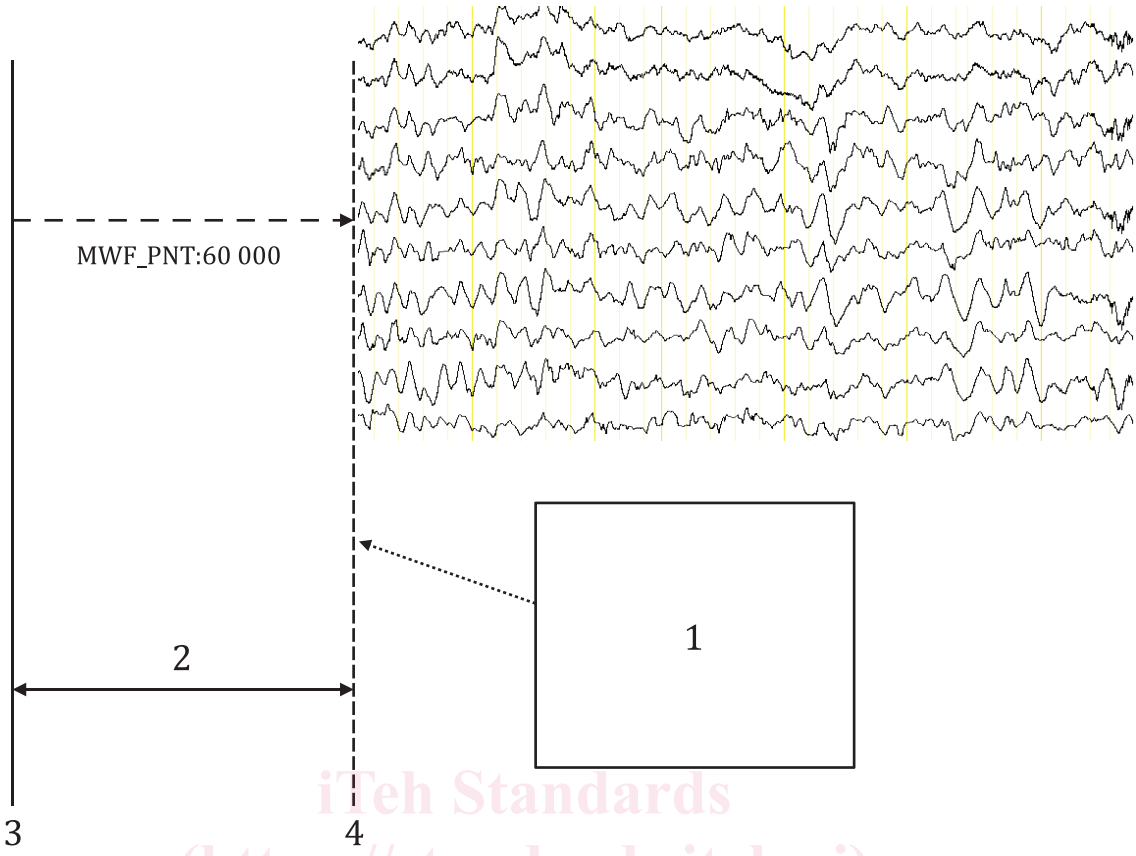
synchronization between the waveform streams and these parametric observations. In addition, it is necessary to capture the state of the photic stimulator at the time the data was acquired.

NOTE For EEG examinations, photic stimulators are used to investigate anomalous brain activity triggered by specific visual stimuli, such as flashing lights or other patterns.

The reference time used for synchronization starts counting from the beginning of the examination period. The data recording system shall establish the reference time for each data point using the recorded examination time. The reading system can then establish synchronization between data points by correlating the acquisition time for each data point.

The reference time of waveforms such as EEGs are described using the pointer tag (MWF_PNT). The reference time of events such as photic stimulator information (stimulator period, frequency, mode, duration, etc.) is described using "starting time" item of the event tag (MWF_EVT). The reference time of measurements such as heart rate and respiration rate are described using the "time point" item of the value tag (MWF_VAL). Reference time is indicated as a data pointer that depends on the sampling rate of the waveform frame. The waveform reader system may also achieve data synchronization using pointers of different sampling rate.

For example, in Figure 3, if the sampling interval of a photic stimulator event is 1 second and the sampling interval of EEG waveform is 1 ms, then the point of photic stimulator event becomes 60 s and the point of EEG waveform becomes 60 000 samples at the time of the start of the photic stimulator.



Key

1 Event information
tag: MWF_EVT
code: <photic Stimulator>
starting time: 60 s

2 60 s

3 start of examination

4 stimulator begin

Figure 3 — Time synchronization

6 Waveform encoding

6.1 General

6.1.1 Application of EEG studies

This set of medical waveform format encoding rules (MFER) is aimed at ensuring that the waveforms collected during EEG studies, including PSG examinations, are encoded together with the needed contextual and descriptive information of the EEG examination. The waveforms recorded during EEG studies include “full disclosure waveform” (i.e. comprehensive continuous waveform data covering the entire period of the exam), and “intermittent record waveform” (i.e. waveform records in short segments of particular interest during the exam). Intermittent waveforms are also commonly described as, e.g. “one shot”, “window”, “snapshot”, “snippet”.

6.1.2 Full disclosure waveforms

This form is used when encoding all EEG waveforms during examinations, including the resting period, and the loading period such as photic stimulation. This not only includes encoding of waveform signals from all leads used in the examination but also encoding of a subset of waveforms selected from multiple leads. Note that for full disclosure waveform recording, encoding waveforms for the entire period of the examination within one frame (see Figure 2) significantly reduces the MFER file complexity and simplifies reading of the EEG content.

Encoding of full disclosure waveform shall be done in accordance with ISO 22077-1. The waveform class of these waveforms include EEG_REST (40), EEG_EP (41), EEG_LTRM (43) and others.

6.1.3 Intermittent record waveforms

Intermittent recording of waveforms is used when encoding the waveforms of EEG, etc., using interval records to capture shorter periods of interest during the examination such as resting, photic stimulation, hyperventilation periods or one-shot records taken at random during the examination.

The point of time when the record concerned was taken during the test shall be encoded with using the pointer tag (MWF_PNT).

For example, in Figure 4, if the sampling interval is 1 ms, then the point of information event (point #1) becomes 600 s and the point of EEG waveform becomes 600 000 samples at the time of the start of the examination.

Using the same sampling interval, the point of information event (point #2) becomes 900 s and the point of EEG waveform becomes 9 000 000 samples at the time of the start of the examination.