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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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