
**Health informatics — Medical
waveform format —**

Part 2:
Electrocardiography

*Informatique de santé — Forme d'onde médicale —
Partie 2: Electrocardiographie*



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Published in Switzerland

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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 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 215, *Health informatics*.

This first edition of ISO 22077-2 cancels and replaces ISO/TS 22077-2:2015, which has been technically revised.

The main changes are as follows:

- clarified references in the text for all figures and tables;
- updated [clause 3](#);
- corrected [Figure 4](#), [Figure C.1](#) and [Figure C.4](#);
- deleted the description of "Unique identifier", "Measurement date/time", "Patient information", and "Comment" that are described in ISO 22077-1;
- added and changed the description for some items of [Annex B](#).
- deleted Annex E;

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 standard 12-lead electrocardiography (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, to address the therapeutic requirements, ECG use should not be constrained to specific machine types and manufacturers. Furthermore, the various kinds of patient information contained in ECGs that are extensively studied and shared between health care providers.

This document defines the detailed rules for the electrocardiography waveform format that is encoded according to the medical waveform format encoding rules (MFER). Rules for other waveforms such as long-term ECG (Holter ECG), stress ECG, etc. 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 typically makes diagnoses using 10 s to 15 s ECG waveform measurements; however, longer periods are sometimes required to recognize 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 waveforms, 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 including HL7®¹⁾ CDA, XML, and DICOM®²⁾. 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.

Product capabilities are not limited

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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.

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 representations.

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 it can also be extended to support future formats as well.

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Health informatics — Medical waveform format —

Part 2: Electrocardiography

1 Scope

This document defines the application of medical waveform format encoding rules (MFER) to describe standard electrocardiography waveforms measured in physiological laboratories, hospital wards, clinics, and primary care medical checkups. It covers electrocardiography 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 document include Holter ECG, exercise stress ECG, and real-time ECG waveform encoding used for physiological monitors.

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 following terms and definitions 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

dominant beat

primary heart beat extracted from typical beats for each lead in a 12-lead ECG

Note 1 to entry: The dominant beat is the beat used for primary measurement and analysis in a 12-lead ECG.

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

3.1.2

average beat

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

Note 1 to entry: The average beat is used for the same purpose as the dominant beat.

Note 2 to entry: This is a waveform with the average value of waveforms excluding the abnormal beats for each lead.