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Part 2: Electrocardiography

Informatique de santé — Forme d'onde médicale —

Partie 2: Electrocardiographie

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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 standard 12-lead electrocardiogram (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, it is essential that to address the therapeutic requirements, ECG use is not constrained to specific machine types and manufacturers. Furthermore, there is great interest in the various kinds of patient information contained in ECGs that are extensively studied and shared between health care providers.

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 2: Electrocardiography

1 Scope

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

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
dominant beat
typical heart beat used for measurement and analysis in standard 12-lead ECG

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

3.2
average beat
typical heart beat used for measurement and analysis in standard 12-lead ECG

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

3.3
median beat
typical heart beat used for measurement and analysis in standard 12-lead ECG

Note 1 to entry: This is a waveform with the median value of waveforms excluding the abnormal beats for each lead.

3.4
tag
identifier code for a semantic concept