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BSI Standards Publication

Health informatics — Medical waveform format

Part 4: Stress test electrocardiography



National foreword

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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 <u>www.iso.</u> <u>org/iso/foreword.html</u>.

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 <u>www.iso.org/members.html</u>.

Introduction

0.1 General

Stress test electrocardiography is an examination that is frequently used. It is used to check the changes in biological phenomena such as electrocardiogram or blood pressure that occur during cardiac stress. Cardiac stress can be seen via exercise or by intravenous pharmacological stimulation. The purpose of this examination is to find cardiac abnormalities, such as myocardial ischemia disease or arrhythmia during exertion, and to check the athletic capability of the cardiopulmonary function.

This document defines the detailed rules of stress test electrocardiogram waveform format that is encoded according to the Medical waveform Format Encoding Rules (MFER). In addition to basic rules defined in ISO 22077-1, there are rules for ECG waveforms electrocardiography (12lead ECG, etc.) and long-term electrocardiography (Holter ECG) that are contained in other MFER technical specifications, i.e. ISO/TS 22077-2 and ISO/TS 22077-3. Please refer to those specifications for additional information.

0.2 Information package added to the electrocardiogram

The stress test checks the changes in the electrocardiogram during exercise against the resting electrocardiogram. To correctly interpret the changes, we also need to capture other waveforms such as the blood pressure, respiration gas, SpO_2 and the load information. These should be put into a single package to be delivered to a third party such as a healthcare provider.

The purpose of this document is to describe waveforms of different nature in the package and how they can be synchronized in order to be interpreted simultaneously by the recipient of the package.

0.3 About electrocardiography waveform encoding in MFER

It is recommended to store the original waveforms as much as possible, i.e. waveforms are not irreversible compressed or filtered. This is to avoid losing the information contained in the original waveform when reusing the waveform in research, etc. It is desirable to perform the processing (e.g., Synthesized lead or filtering) needed for encoded waveforms. The configuration and condition of an electrocardiogram recording may be encoded with waveform data to assure reproduction of electrocardiographic representation when using a system such as electronic medical records. However, it is entrusted to the system whether those can or cannot be reproduced using this information. There are often large drift noises and EMGs on electrocardiograms during exercise stress tests. Some devices perform special signal processing to remove these noises. And the system might not be able to perform the same signal processing to reproduce the electrocardiogram that was recorded. In such a case, in addition to the original waveform, storing the waveform after signal processing is also an option.

Health informatics — Medical waveform format —

Part 4: Stress test electrocardiography

1 Scope

This document defines the application of Medical waveform Format Encoding Rules (MFER) to describe stress test electrocardiography, which is one of the outputs of exercise, pharmacological and cardiopulmonary stress test. MFER performed in physiological laboratories, healthcare clinics, etc.

This document covers not only the electrocardiogram waveform but also the description of related stress information and biological signals, e.g. blood pressure, respiration gas, SpO₂, etc..

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/TS 22077-2, Health informatics — Medical waveform format — Part 2: Electrocardiography

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

3 Terms, definitions, symbols and abbreviations

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions 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 <u>http://www.electropedia.org/</u>

3.1.1

abstract waveform

single beat ECG waveform which is extracted from all ECG waveform during examination period, including the waveform which did the signal processing such as averaging

3.1.2

intermittent recording

recording electrocardiogram for a given period of time at a preset interval of time

3.1.3

full disclosure waveform

electrocardiographic waveform covering the entire time from the *resting period* (3.1.4) to the *recovery period* (3.1.7) during cardiac stress test

3.1.4

resting period

phase before loading of stress (by exercise or medication) to the patient's heart