First edition
2009-05-01

Health informatics — Standard communication protocol —

Part 91064: Computer-assisted electrocardiography

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —

Partie 91064: Protocole de communication standard pour l'électrocardiographie assistée par ordinateur

Reference number
ISO 11073-91064:2009(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11073-91064 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

The electrocardiogram (ECG) is a recording of voltage changes transmitted to the body surface by electrical events in the heart muscle, providing direct evidence of cardiac rhythm and conduction, and indirect evidence of certain aspects of myocardial anatomy, blood supply and function. During its propagation to the surface, extracardiac tissues may intervene and influence the ECG.

Electrocardiography has been used for many years as a key, non-invasive method in the diagnosis and early detection of coronary heart disease, which is the leading cause of mortality in western countries. In 1993, it was estimated that more than 100 million standard ECGs are recorded yearly in the European Community (EC) for routine diagnostic and screening purposes at an estimated cost of more than 1,2 billion € per year.

Almost all newer electrocardiographs nowadays use digital recording, interpretation and communication techniques. These stand-alone, microcomputer based machines can be connected to each other, and to larger minicomputer-based management servers for long-term storage and serial comparison. To this end, various manufacturers have used different techniques.

It is in the general public interest for users not to be restricted in their options by incompatible technical features and services of different systems. ECG processing is increasingly being integrated with various other data processing in health care. This evolution shall have considerable impact on the storage and communication of ECG data. There are many different end-users who for different purposes (support of patient care, management, research and education) want to obtain a copy of the signal data, of the interpretive report and/or measurement results. Being one of the very first systems for medical decision support, computerized ECG interpretation stretches from departments of cardiology in hospitals, to general practitioners in primary care and health care centres. In life-threatening acute myocardial infarction, ECGs are being used in ambulances by paramedical personnel to assess the necessity for administering thrombolytic agents, with long-distance monitoring whenever possible.

To enable the exchange of information between various systems it was of utmost importance that a standard communications protocol for computer-aided electrocardiography (SCP-ECG) had to be established, as defined in this document. The primary aim of this document is to specify a data format for transferring ECG reports and data from any vendor's computerized ECG recorder to any other vendor's central ECG management system. The same standard should also allow standardized transfer of digitized ECG data and results between various computer systems.

Under the standard communication protocol (SCP) the contents and format of the ECG waveform data and the measurements from ECG devices of different manufacturers are not expected to be identical. As a result, the determination of the suitability of a device and/or system for any particular application remains with the user/purchaser. The following possible uses of ECG records require special attention:

— serial comparison of ECGs and interpretations;

— plot formats of ECGs;

— maintaining audit trail of edits;

— bi-directional communication and remote query.

The user is cautioned to make sure that the data contents and format of the waveform data, measurements, and the interpretive statements meet his or her specific needs. If more than one type of ECG device and/or database management system are interconnected, the user is also advised to verify with the manufacturers that the data from different systems are compatible with each other and with the user’s needs.

In order to understand this document, the reader needs some basic understanding of electrocardiology, electrocardiography and signal processing.

This part of ISO 11073 relates to the conventional recording of the electrocardiogram, i.e. the so-called standard 12-lead electrocardiogram and the vectorcardiogram (VCG). Initially, the electrical connections used for recording the ECG were made to the limbs only. These connections to the right arm (RA), left arm (LA), left leg (LL) and right leg (RL) were introduced by Einthoven. The electrical variations detected by these leads are algebraically combined to form the bipolar leads I, II and III. Lead I, for example, records the difference between the voltages of the electrodes placed on the left arm and the right arm. The unipolar electrocardiographic leads (aVR, aVL, aVF and the precordial leads V1 to V6) were introduced much later, starting in 1933. In these leads, potentials are recorded at one location with respect to a level which does not vary significantly in electrical activity during cardiac contraction. The “augmented” limb lead potentials are recorded with reference to the average potential of (L+F), (R+F) and (L+R) respectively. The unipolar chest leads are recorded with reference to the average potential of $\frac{(RA+RL+LL)}{3}$ which is called the Wilson “central terminal” (CT). In vectorcardiography, recordings are made of three mutually perpendicular leads, running parallel to one of the rectilinear coordinate axes of the body. The axes are the X-axis going right to left, the Y-axis with a top to bottom orientation and the Z or front to back axis.

In some research centres, so-called body surface maps are obtained by placing many (from 24 to 124 or even more) closely-spaced electrodes around the torso. This part of ISO 11073 has not been designed to handle exchanges of such recordings, although future extensions could be made to this end. This part of ISO 11073 has also not been designed to exchange specialized recordings of intracardiac potentials or of the so-called Holter or other long-term ECG recordings made for monitoring cardiac rhythm. This part of ISO 11073 also does not address exercise ECG recordings.

ECG computer processing can be reduced to three principal stages:

1) data acquisition, encoding, transmission and storage;

2) pattern recognition and feature extraction, i.e. ECG measurement;

3) diagnostic classification.

In each of these stages there are important needs for standardization and quality assurance testing. The scope of this part of ISO 11073 is confined to the first of these three stages.

The various data sections that shall be transmitted by means of the standard ECG communications protocol are defined in Clause 5. Minimum requirements for data encoding and compression are defined in Clause 6.

The compliance categories defined in Annex B provide users and manufacturers of ECG devices and/or systems with a relatively simple codification of SCP-ECG related features and information content that may be provided by a specific device. Two data format categories have been defined based on information content as in Table 1.

Table 1 — Data format categories for compliance specifications

Category	Data sections required	Content description
I	0, 1, [2], 3, 6, (7), (8), (10)	Demographics, and ECG rhythm data (uncompressed or with lossless compression)
II	0, 1, [2], 3, 4, 5, 6, (7), (8), (10)	Demographics, ECG rhythm data (uncompressed, with lossless compression or with high compression), and reference beats
NOTE 1 Square brackets [ ] indicate that data section 2 is required if Huffman encoding has been used.		
NOTE 2 Parentheses ( ) indicate that these data sections are optional for export.		

A further category may be added in future versions in order to fulfil the specific needs of ECG devices used in other applications (such as telemedicine or homecare).

All devices stating an SCP-ECG data format category shall import at minimum data sections 0, 1, 3, 6, 7 and 8. All categories may have additional sections added (e.g. 9, 10, 11). Manufacturer-specific data shall be optionally included only in manufacturer-specific fields, bytes and data blocks that have been defined in the document. Reserved, unspecified and undefined fields, bytes or data blocks shall not be used for manufacturer-specific data.

For a particular device, an SCP-ECG compliance statement lists data format category(ies) for export (i.e. acquiring and making available an SCP-ECG record) and import (i.e. accepting, and making available to a user, an SCP-ECG record). A device may also state its ability to transfer (i.e. making available an SCP-ECG record without changing its data format, for example, exporting a record that was previously imported). (These terms are precisely defined in Annex B for the purpose of this part of ISO 11073).

The selection and definition of ECG-specific high-level syntaxes for transfer of messages and data host-to-hosts, such as EDIFACT or ASN.1, are beyond the scope of this part of ISO 11073.