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Health informatics — A case study on establishing standardized measurement data in cardiac examination reports

Informatique de santé — Étude de cas sur l'établissement de données de mesure normalisées dans les rapports d'examens cardiaques

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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*.

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.

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Introduction

Various clinical examinations, such as ultrasonic echocardiography (UCG), electrocardiogram (ECG) and coronary angiogram (CAG) are used for diagnosis and treatment of cardiovascular diseases. Cardiologists not only use imaging during those examinations but also numerical measurement data obtained from clinician observation and the various medical device systems used in daily clinical examination routines. They also consider information such as the patient's symptoms and the examination procedure(s) performed. These data are stored with images and waveforms in standard formats such as DICOM®[1)][1] and MFER[2], or are stored as non-interoperable, manufacturer-specific data formats.

In cardiac examinations, multiple devices are used simultaneously for diagnostic and therapeutic purposes, and corresponding reports are produced by each device and system. This includes “cath labs” (Cardiac Catheterization Lab) where multiple device modalities (e.g. haemodynamic monitoring and imaging) are utilized and reports generated; however, as pointed out above there is little consistency in the resulting reports, especially with respect to parametric data.

The contents of data required for these cardiac examination reports is generally different for each medical facility, as well as clinicians performing the procedures. In addition to these general interoperability challenges, medical researchers want to utilize such data for secondary purposes utilizing a clinical database or registry to support, for example, nation-wide” big data” analytics research programs. In order to support this secondary use, one must both collect the data generated from devices and reporting systems and then register that data used in the cardiovascular division in a clinical information database. However, since the contents and formats of the examination data are not standardized and consistent, special conversion is required. The cost of machine conversion is typically high, and there are increased risks of human error when an operator re-enters data manually.

The reporting of cardiac examination export measurement data (CE-EMD) to clinical databases has not been standardized for numerous reasons, including the following:

— Requested CE-EMD content varies depending on the medical facility and care providers/clinicians;

— Produced CE-EMD is different for each manufacturer;

— Name and contents (data elements) of CE-EMD are not uniform;

— Format of CE-EMD is often not represented or “coded” according to any standard.

Figure A.1 provides an overview of the use context for this document. Although guidance for the creation of radiology reports has been developed (e.g. in IHE and DICOM), this is not the case for cardiology examination reporting.

This document provides an overview of the rules on how to establish and maintain standardized CE-EMD report content based on the SEAMAT program in Japan as applied to cardiac examination reports, which has been organized to present the approach that successfully employed in both establishing and maintaining CE-EMD specifications. This approach could be as a reference for applying in other national or regional contexts.

Annex A provides a more detailed history of the SEAMAT program.

1) 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.

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Health informatics — A case study on establishing standardized measurement data in cardiac examination reports

1 Scope

This document reposts a case study on how to establish and maintain standardized cardiac examination export measurement data (CE-EMD), especially for enabling its secondary use for medical research. The document includes information for CE-EMD on:

— Building a representative coalition of stakeholders to identify and establish specifications;

— Standardizing both the content and format in reports;

— Maintaining and extending the specifications over time.

Out-of-scope for this document are any requirements for specific CE-EMD content or formatting. Also, this document is limited to cardiac examination reporting, and does not encompass other clinical care areas or reporting that have been standardized.

2 Normative references

There are no normative references in this document.

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
cardiac examination – export measurement data
CE-EMD
numeric and text data that is exported from medical devices and reporting systems during cardiology examinations

3.1.2
reporting system
computer system or software application with function to create a report containing CE-EMD for diagnosis and treatment

3.1.3
secondary use
using data for purposes other than clinical

Note 1 to entry: In this document, cardiac examination data is used for medical research, etc.

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