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Health informatics - Testing of physiological measurement software - Part 1: General

Bewertung von physiologischen Analysesystemen

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Foreword

This document (CEN/TS 15127-1:2005) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This Technical Specification was first produced by a project team funded by the British Standards Institute as a contribution to the work of CEN/TC251/WGIV. It is a contribution towards work item WI050 “Evaluation of Physiological Analysis Systems”. The work item identified two priority medical areas: Nuclear Medicine Analysis Systems and ElectroCardioGram Analysis Systems. Much background work has been done on Nuclear Medicine Systems and was used by the team in production of this document. This technical specification is intended to be a generic base technical specification, which can be adapted to be specific to particular medical areas.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this CEN Technical Specification: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

Motivation - nature of test data

Many Diagnostic Healthcare Procedures that involve the acquisition of patient data by means of one or more Medical Devices produce results in the form of an Acquired Patient Data Array. Examples are a time series of Medical Image data stored in a 3-dimensional array, and a set of ECG waveform data stored in a 2-dimensional array. It is often the case that such data arrays are subjected to computer processing in order to derive data in a more simple form as an aid to clinical diagnosis. Ideally, the same diagnostic test performed on the same patient using different equipment should produce the same final result. In practice, however, reproducibility problems can arise due to differences in - the data acquisition protocol (e.g. patient position, image data acquisition frame rate), or differences in the means of data processing. This latter step is amenable to evaluation by the use of standard test data, which can be employed by users of different data processing systems to compare their results against those obtained in other centres.

In principle, various types of test data can be used to assess the validity of results produced by a medical software application that produces quantitative results. In general, such test data may comprise real clinical data, simulated (synthetic) data, or a combination of the two (hybrid data). In the case of real clinical data, the input to the data processing step will be the primary output from a Medical Device (e.g. raw image data). The software referred to in this technical specification should thus be considered as being associated with the second stage of a two-stage process: data acquisition followed by data processing.

This CEN Technical Specification describes a framework for specifying a set of test data to be submitted to a medical software application. The framework allows for the production of a medical application specific technical specification, which allows a number of medical device/processing system users to obtain results using the same test data set comprising one or more Acquired Patient Data Arrays, plus associated descriptive data. The descriptive data will include firstly descriptions of the way in which the test data was created to enable appropriate processing to be performed and secondly to specify the results that shall be obtained by the application. For historical background and review of previous work, see Annex A.

This CEN Technical Specification specifies the components that must be included in the set of test data intended to test the performance of software designed to process data in the form of one or more Acquired Patient Data Arrays and possible associated data, such as Region of Interest (ROI) data.

Relevant bodies

In order to ensure quality and consistency in the application of test data sets, three bodies may be identified:

The first is a test data creation/approval body with the responsibility of approving the test data as appropriate for the test described. The second is a testing body (that performs the testing) which might be an independent testing laboratory or a user. Lastly, a body that evaluates the test results obtained by testing bodies, potentially for certification.

NOTE the creating and evaluating functions may be performed by the same body. The evaluating body may issue formal certification

Test data set

This could comprise for example: one or more Acquired Patient Data Arrays which could be submitted for processing; essential details concerning how the test data arrays were obtained (eg. array size, dimension details, etc); the names of the parameters to be derived by the processing; and finally the expected values for the derived parameters.

The test data set is specified in Clause 4.

Descriptive data sections

These sections could be for example:

— Title of document;

— Name of diagnostic procedure for which the test data set is relevant;

— Description of diagnostic procedure;

— How the test data set should be used in practice, and its results;

— Expected value(s) for the derived parameter(s) which may or may not be supplied to Testing Bodies (e.g. users).

The results of tests may be used for audit or certification purposes. The descriptive data sections are specified in Clause 5.

1 Scope

1.1 In scope

The means to specify test data sets, documenting the creation of the test data, and the use of the test data for the testing, possibly for certification purposes, of medical software which is designed to process data in the form of one or more arrays of acquired patient and associated data.

1.2 Out of scope

The means by which medical software is certified or produced.

The nomination of bodies to perform functions related to the creation and use of Test Data Sets.

The working practices of bodies responsible for the creation or use of test data sets or bodies responsible for the evaluation of the test results.

The means by which the test data are created

2 Normative references

The following referenced documents are indispensable for the application 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.

EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)*

ISO 9126, *Information Technology – Software product evaluation – Quality characteristics and guidelines for their use*

3 Terms, definitions and abbreviations

3.1 Abbreviations

ECG	Electrocardiogram
LUT	Look-Up Table
ROI	Region of Interest
TDS	Test data set

3.2 Terms and definitions

3.2.1
acquired patient data array
healthcare procedure product in the form of a data array of one or more dimensions obtained from a process of measurement involving the body of a patient