SLOVENSKI STANDARD
SIST EN 62304:2006/A1:2015

01-december-2015

Programska oprema za medicinske aparate - Procesi v življenjskem ciklu programske opreme - Dopolnilo A1

Medical device software - Software life-cycle processes

Medizingeräte-Software - Software-Lebenszyklus-Prozesse

Logiciels de dispositifs médicaux - Processus du cycle de vie du logiciel

Ta slovenski standard je istoveten z: **EN 62304:2006/A1:2015**

ICS:

13.020.60	Življenjski ciklusi izdelkov	Product life-cycles
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN 62304:2006/A1:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62304:2006/A1

October 2015

ICS 11.040

English Version

Medical device software - Software life-cycle processes (IEC 62304:2006/A1:2015)

Logiciels de dispositifs médicaux - Processus du cycle de vie du logiciel (IEC 62304:2006/A1:2015)

Medizingeräte-Software - Software-Lebenszyklus-Prozesse (IEC 62304:2006/A1:2015)

This amendment A1 modifies the European Standard EN 62304:2006; it was approved by CENELEC on 2015-07-31. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European Foreword

The text of document 62A/1007/FDIS, future IEC 62304:2006/A1, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 62304:2006/A1:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-05-01
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-07-31

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, 98/79/EC, 90/385/EEC see informative Annex ZZ, included in EN 62304:2006/corrigendum Nov. 2008.

Endorsement notice

The text of the International Standard IEC 62304:2006/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

Replace the existing references with the following:

IEC 60601-1:2005	NOTE	Harmonized as EN 60601-1:2006.
IEC 60601-1:2005/AMD1:2012	NOTE	Harmonized as EN 60601-1:2006/A1:2013.
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996.
IEC 60601-1-4:1996/AMD1:1999	NOTE	Harmonized as EN 60601-1-4:1996/A1:1999.
IEC 60601-1-6	NOTE	Harmonized as EN 60601-1-6.
IEC 61508-3	NOTE	Harmonized as EN 61508-3.
IEC 61010-1:2010	NOTE	Harmonized as EN 61010-1:2010.
ISO 9000:2005	NOTE	Harmonized as EN ISO 9000:2005.
ISO 9001:2008	NOTE	Harmonized as EN ISO 9001:2008.
ISO 13485:2003	NOTE	Harmonized as EN ISO 13485:2003.

IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015.
IEC 82304-1	NOTE	Harmonized as EN 82304-1 [1)]

1) At draft stage.

IEC 62304

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INTERNATIONAL STANDARD

AMENDMENT 1

Medical device software – Software life cycle processes

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040

ISBN 978-2-8322-2720-6

FOREWORD

This amendment has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice and ISO Technical Committee 210, Quality management and corresponding general aspects for MEDICAL DEVICES.

This publication is published as a double logo standard.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/1007/FDIS	62A/1014/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 30 P-members out of 30 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION TO THE AMENDMENT

The first edition of IEC 62304 was published in 2006. This amendment is intended to add requirements to deal with LEGACY SOFTWARE, where the software design is prior to the existence of the current version, to assist manufacturers who must show compliance to the standard to meet European Directives. Software safety classification changes needed for this amendment include clarification of requirements and updating of the software safety classification to include a risk-based approach. Work is continuing in parallel to develop the second edition of IEC 62304.

FOREWORD

Add the following note at the end of the Foreword:

NOTE The attention of National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

Replace, in the second paragraph, the existing third sentence with the following:

Each life cycle PROCESS consists of a set of ACTIVITIES, with most ACTIVITIES consisting of a set of TASKS.

*Replace, in the first sentence of the fourth paragraph, the phrase "*contributing factor to a HAZARD*" with "* contributing factor to a HAZARDOUS SITUATION*"*.

Replace, in the second sentence of the fourth paragraph, the term, "HAZARDS" *with* "HAZARDOUS SITUATIONS".

Add, after the existing sixth paragraph, the following new paragraph:

Amendment 1 updates the standard to add requirements to deal with LEGACY SOFTWARE, where the software design is prior to the existence of the current version, to assist manufacturers who must show compliance to the standard to meet European Directives. Software safety classification changes include clarification of requirements and updating of the software safety classification to include a risk-based approach.

1 Scope

1.2 * Field of application

Replace the entire existing text of this subclause with the following:

This standard applies to the development and maintenance of MEDICAL DEVICE SOFTWARE when software is itself a MEDICAL DEVICE or when software is an embedded or integral part of the final MEDICAL DEVICE.

NOTE 1 This standard can be used in the development and maintenance of software that is itself a medical device. However, additional development activities are needed at the system level before this type of software can be placed into service. These system activities are not covered by this standard, but can be found in IEC 82304-1[1] [22].

This standard describes PROCESSES that are intended to be applied to software which executes on a processor or which is executed by other software (for example an interpreter) which executes on a processor.

This standard applies regardless of the persistent storage device(s) used to store the software (for example: hard disk, optical disk, permanent or flash memory).

This standard applies regardless of the method of delivery of the software (for example: transmission by network or email, optical disk, flash memory or EEPROM). The method of software delivery itself is not considered MEDICAL DEVICE SOFTWARE.

This standard does not cover validation and final release of the MEDICAL DEVICE, even when the MEDICAL DEVICE consists entirely of software.

NOTE 2 If a medical device incorporates embedded software intended to be executed on a processor, the requirements of this standard apply to the software, including the requirements concerning software of unknown provenance (see 8.1.2).

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1 In preparation.

NOTE 3 Validation and other development activities are needed at the system level before the software and medical device can be placed into service. These system activities are not covered by this standard, but can be found in related product standards (e.g., IEC 60601-1, IEC 82304-1, etc.).

1.4 Compliance

Delete, in the second paragraph, the instruction “See Annex D.”

Add, after existing Note 4, the following new note:

NOTE 5 For compliance of LEGACY SOFTWARE see 4.4.

3 * Terms and definitions

3.2
ANOMALY

Replace, in the definition, "SOFTWARE PRODUCTS" *with* "MEDICAL DEVICE SOFTWARE".

Replace the existing source reference with the following note:

NOTE Based on IEEE 1044:1993, definition 3.1.

3.4
CHANGE REQUEST

Replace "SOFTWARE PRODUCT" *with* "MEDICAL DEVICE SOFTWARE".

3.5
CONFIGURATION ITEM

Replace, in the note, "ISO/IEC 12207:1995, definition 3.6" *with* "ISO/IEC 12207:2008, 4.7".

3.7
EVALUATION

Replace the existing source reference with "[ISO/IEC 12207:2008, 4.12]".

3.8
HARM

Replace the existing source reference with "[ISO 14971:2007, 2.2]".

3.9
HAZARD

Replace the existing source reference with "[ISO 14971:2007, 2.3]".

3.10
MANUFACTURER

Add the following new notes:

NOTE 1 Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

NOTE 2 For a definition of labelling, see ISO 13485:2003, definition 3.6.

Replace the existing source reference with "[ISO 14971:2007, 2.8]".

3.11
MEDICAL DEVICE

Add the following new note:

NOTE 3 In conjunction with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 the term "medical device" assumes the same meaning as ME EQUIPMENT or ME SYSTEM (which are defined terms of IEC 60601-1).

3.12
MEDICAL DEVICE SOFTWARE

Replace the existing definition with the following:

SOFTWARE SYSTEM that has been developed for the purpose of being incorporated into the MEDICAL DEVICE being developed or that is intended for use as a MEDICAL DEVICE

NOTE This includes a MEDICAL DEVICE software product, which then is a MEDICAL DEVICE in its own right.

3.13
PROBLEM REPORT

Replace, in the definition and in Notes 1 and 2, "SOFTWARE PRODUCT" *with* "MEDICAL DEVICE SOFTWARE" *(4 times)*.

3.16
RISK

Replace the existing source reference with "[ISO 14971:2007, 2.16]".

3.17
RISK ANALYSIS

Replace the existing source reference with "[ISO 14971:2007, 2.17]".

3.18
RISK CONTROL

Replace the existing source reference with "[ISO 14971:2007, 2.19]".

3.19
RISK MANAGEMENT

Replace the existing source reference with "[ISO 14971:2007, 2.22, modified – The phrase "and monitoring" has been removed]".

3.20
RISK MANAGEMENT FILE

Replace the existing source reference with "[ISO 14971:2007, 2.23]".

3.21
SAFETY

Replace the existing source reference with "[ISO 14971:2007, 2.24]".

3.22
SECURITY

Replace the existing definition with the following:

protection of information and data so that unauthorized persons or systems cannot read or modify them an authorized persons or systems are not denied access to them.

NOTE Based on ISO/IEC 12207:2008, 4.39.

3.23
SERIOUS INJURY

Delete, in the first line of the definition, the words "directly or indirectly".

3.24
SOFTWARE DEVELOPMENT LIFE CYCLE MODEL

Delete, in the second line of the definition, the phrase "for manufacturing*".*

Replace, in the first dashed item, the words "a SOFTWARE PRODUCT" *with* "MEDICAL DEVICE SOFTWARE".

3.25
SOFTWARE ITEM

Replace the existing definition with the following:

any identifiable part of a computer program, i.e., source code, object code, control code, control data, or a collection of these items

NOTE 1 Three terms identify the software decomposition. The top level is the SOFTWARE SYSTEM. The lowest level that is not further decomposed is the SOFTWARE UNIT. All levels of composition, including the top and bottom levels, can be called SOFTWARE ITEMS. A SOFTWARE SYSTEM, then, is composed of one or more SOFTWARE ITEMS, and each SOFTWARE ITEM is composed of one or more SOFTWARE UNITS or decomposable SOFTWARE ITEMS. The responsibility is left to the MANUFACTURER to provide the granularity of the SOFTWARE ITEMS and SOFTWARE UNITS.

NOTE 2 Based on ISO/IEC 90003:2004, 3.14 and ISO/IEC 12207:2008, 4.41.

3.26
SOFTWARE PRODUCT

Delete the existing term and definition and add "Not used".

3.28
SOFTWARE UNIT

Replace the existing note by the following:

NOTE The granularity of SOFTWARE UNITS is defined by the MANUFACTURER (see B.3).

3.29
SOUP
software of unknown provenance (acronym)

*Replace, in the third line of the definition, "*software previously developed*" with "*SOFTWARE ITEM previously developed*"*

Add the following new note:

NOTE A MEDICAL DEVICE SOFTWARE SYSTEM in itself cannot be claimed to be SOUP.

3.30
SYSTEM

Replace the existing source reference with the following note:

NOTE Based on ISO/IEC 12207:2008, 4.48.

3.32
TRACEABILITY

Add the following new note:

NOTE Requirements, architecture, risk control measures, etc. are examples of deliverables of the development PROCESS.

3.34
VERSION

Replace, in the existing text of Note1, the words "a SOFTWARE PRODUCT" *with* "MEDICAL DEVICE SOFTWARE".

Replace the existing text of Note 2 with the following

NOTE 2 Based on ISO/IEC 12207:2008, 4.56.

Add the following new definitions:

3.35
HAZARDOUS SITUATION
circumstance in which people, property or the environment are exposed to one or more HAZARD(S)

[SOURCE: ISO 14971:2007, 2.4]

3.36
LEGACY SOFTWARE
MEDICAL DEVICE SOFTWARE which was legally placed on the market and is still marketed today but for which there is insufficient objective evidence that it was developed in compliance with the current version of this standard

3.37
RELEASE
particular VERSION of a CONFIGURATION ITEM that is made available for a specific purpose

NOTE Based on ISO/IEC 12207:2008, definition 4.35.

3.38
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

NOTE 1 Adapted from ISO/IEC Guide 51:1999, definition 3.9.

NOTE 2 ISO/IEC Guide 51:1999, definition 3.9 uses the term “protective measures” rather than “RISK CONTROL measures.” However, in the context of this International Standard, “protective measures” are only one option for controlling RISK as described in 6.2 [of ISO 14971:2007].

[SOURCE: ISO 14971:2007, 2.15].

3.39
RISK ESTIMATION
PROCESS used to assign values to the probability of occurrence of HARM and the severity of that HARM

[SOURCE: ISO 14971:2007 2.20]

3.40
RISK EVALUATION
PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO 14971:2007 2.21]