ICS 11.040, 11.040.01, 35.240.80

SLOVENSKÁ TECHNICKÁ NORMA

Máj 2016

STN	**Softvér zdravotníckych prístrojov. Procesy ovplyvňujúce životný cyklus softvéru. Zmena A1**	**STN EN 62304/A1** 36 4895

Medical device software - Software life-cycle processes

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/16

STN EN 62304 z februára 2007 sa bez zmeny A1 môže používať do 31. 07. 2018.

Obsahuje: EN 62304:2006/A1:2015, IEC 62304:2006/AMD1:2015

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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

Ref. No. EN 62304:2006/A1:2015 E

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

Edition 1.0 2015-06

INTERNATIONAL STANDARD

AMENDMENT 1

Medical device software – Software life cycle processes

IEC 62304:2006-05/AMD1:2015-06(en)

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IEC 62304

Edition 1.0 2015-06

INTERNATIONAL STANDARD

AMENDMENT 1

Medical device software – Software life cycle processes

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040

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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.

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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.).