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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 62304:2006+A1:2015 sisaldab Euroopa standardi EN 62304:2006 ingliskeelset teksti ja selle muudatuse A1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 62304:2006+A1:2015 consists of the English text of the European standard EN 62304:2006 and its amendment A1:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 12.07.2006, muudatus A1 16.10.2015.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. Date of Availability of the European standard is 12.07.2006, for A1 16.12.2015.
Sellesse standardisse on muudatus A1 sisse viidud ja tehtud muudatused tähistatud topeltpüst-kriipsuga lehe välisveerisel. Parandusega AC lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega ▌AC⟩ ⟨AC▐. Selles standardis on rahvusvahelise standardi ühismuudatused tähistatud püstkriipsuga teksti välimisel veerisel. Standard on kättesaadav Eesti Standardi-keskusest.	The amendment A1 has been incorporated into this standard and changes have been marked by a double vertical line on the outer row of the page. The start and finish of text introduced or altered by amendment AC is indicated in the text by symbols ▌AC⟩ ⟨AC▐. Common modifications has been incorporated into this international standard and changes have been marked by a vertical line on the outer row of the page. The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62304:2006 + A1

July 2006, October 2015

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English Version

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

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

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

This European Standard was approved by CENELEC on 2006-06-01. Amendment A1 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.

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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 E + EN 62304:2006/A1:2015 E

Foreword

The text of document 62A/523/FDIS, future edition 1 of IEC 62304, prepared by a joint working group of SC 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, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62304 on 2006-06-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2007-03-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2009-06-01

In this standard the following print types are used:

– requirements and definitions: in roman type;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– terms used throughout this standard that have been defined in Clause 3 and also given in the index: IN SMALL CAPITALS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance related to that item in Annex B.

Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and system engineering.

〚AC〉 This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directives 93/42/EEC, 90/385/EC and 98/79/EC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC. 〈AC〚

Endorsement notice

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

In this standard common modifications to an international standard are indicated by a vertical line on the outer row of the page.

IEC 62304:2006/A1:2015 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.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

FOREWORD

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International Standard IEC 62304 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. Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and system engineering.

It is published as a dual logo standard.

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

FDIS	Report on voting
62A/523/FDIS	62A/528/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 23 P-members out of 23 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard the following print types are used:

- requirements and definitions: in roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- terms used throughout this standard that have been defined in Clause 3 and also given in the index: in small capitals.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance related to that item in Annex B.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site 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.

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

Software is often an integral part of MEDICAL DEVICE technology. Establishing the SAFETY and effectiveness of a MEDICAL DEVICE containing software requires knowledge of what the software is intended to do and demonstration that the use of the software fulfils those intentions without causing any unacceptable RISKS.

This standard provides a framework of life cycle PROCESSES with ACTIVITIES and TASKS necessary for the safe design and maintenance of MEDICAL DEVICE SOFTWARE. This standard provides requirements for each life cycle PROCESS. Each life cycle PROCESS consists of a set of ACTIVITIES, with most ACTIVITIES consisting of a set of TASKS.

As a basic foundation it is assumed that MEDICAL DEVICE SOFTWARE is developed and maintained within a quality management system (see 4.1) and a RISK MANAGEMENT system (see 4.2). The RISK MANAGEMENT PROCESS is already very well addressed by the International Standard ISO 14971. Therefore IEC 62304 makes use of this advantage simply by a normative reference to ISO 14971. Some minor additional RISK MANAGEMENT requirements are needed for software, especially in the area of identification of contributing software factors related to HAZARDS. These requirements are summarized and captured in Clause 7 as the software RISK MANAGEMENT PROCESS.

Whether software is a contributing factor to a HAZARDOUS SITUATION is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. HAZARDOUS SITUATIONS that could be indirectly caused by software (for example, by providing misleading information that could cause inappropriate treatment to be administered) need to be considered when determining whether software is a contributing factor. The decision to use software to control RISK is made during the RISK CONTROL ACTIVITY of the RISK MANAGEMENT PROCESS. The software RISK MANAGEMENT PROCESS required in this standard has to be embedded in the device RISK MANAGEMENT PROCESS according to ISO 14971.

The software development PROCESS consists of a number of ACTIVITIES. These ACTIVITIES are shown in Figure 1 and described in Clause 5. Because many incidents in the field are related to service or maintenance of MEDICAL DEVICE SYSTEMS including inappropriate software updates and upgrades, the software maintenance PROCESS is considered to be as important as the software development PROCESS. The software maintenance PROCESS is very similar to the software development PROCESS. It is shown in Figure 2 and described in Clause 6.

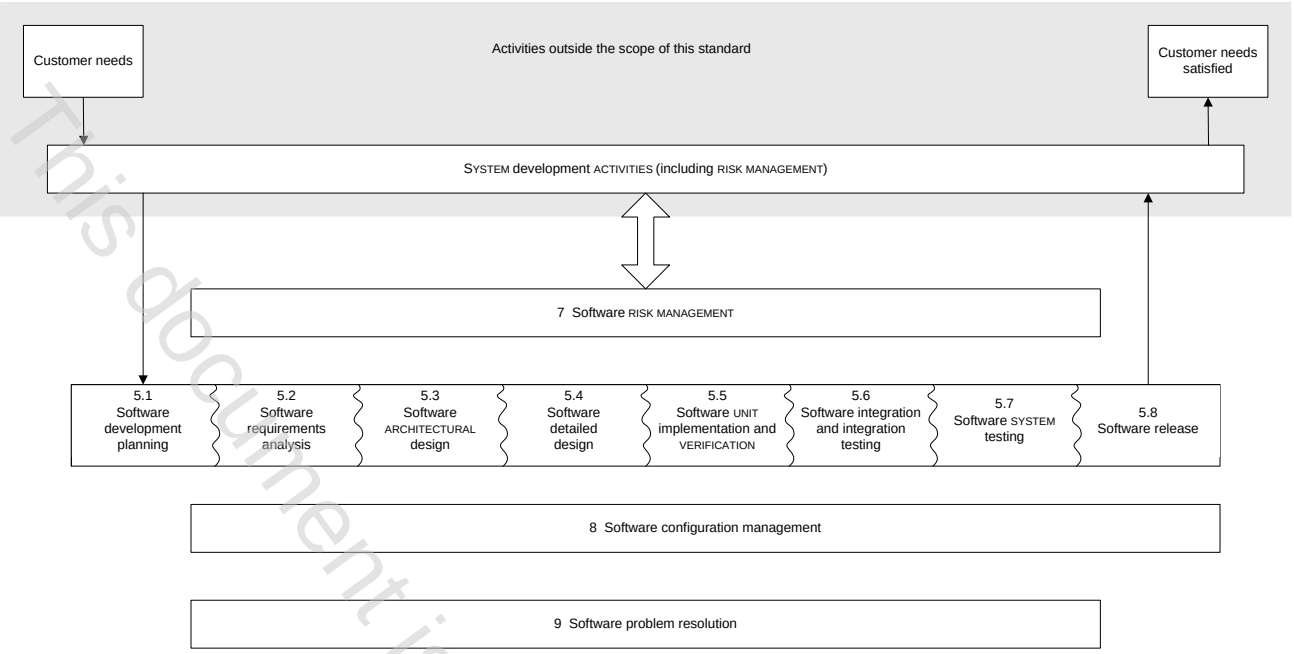

Figure 1 – Overview of software development PROCESSES and ACTIVITIES

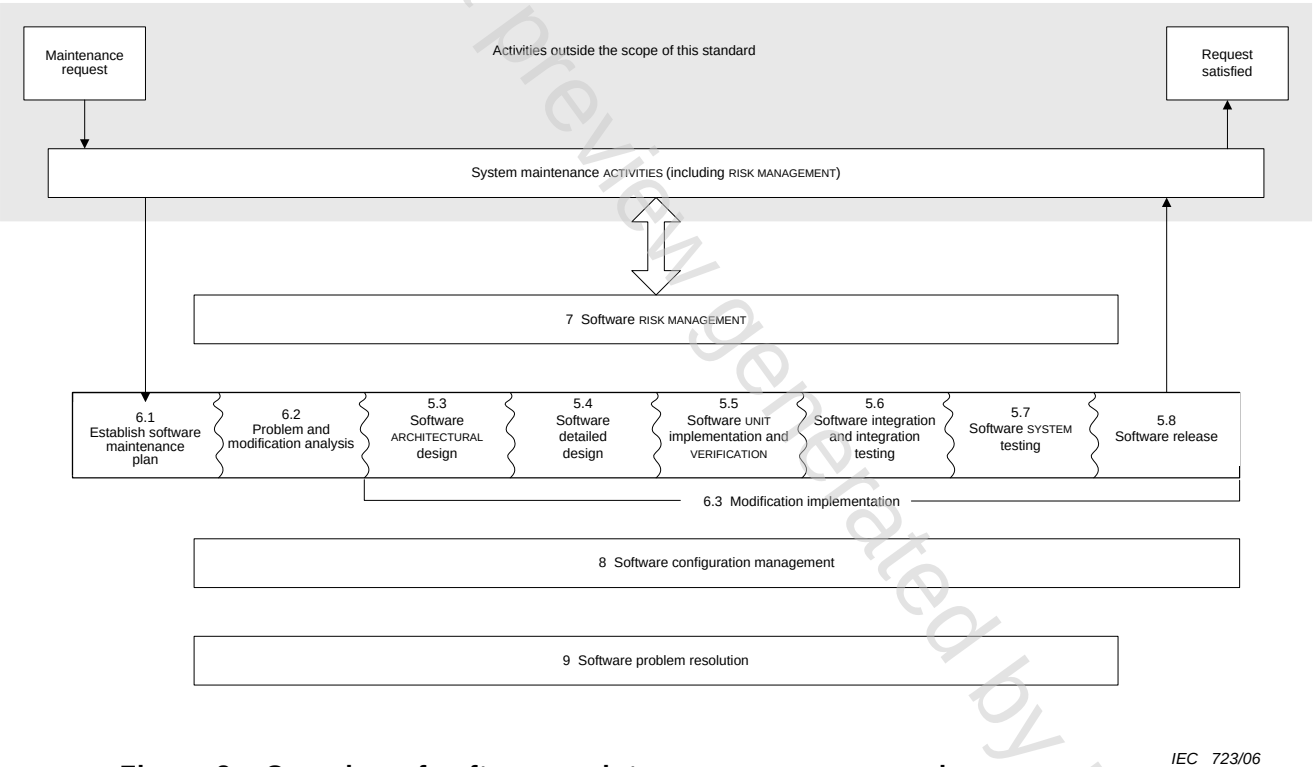

Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES

This standard identifies two additional PROCESSES considered essential for developing safe MEDICAL DEVICE SOFTWARE. They are the software configuration management PROCESS (Clause 8) and the software problem resolution PROCESS (Clause 9).

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.

This standard does not specify an organizational structure for the MANUFACTURER or which part of the organization is to perform which PROCESS, ACTIVITY, or TASK. This standard requires only that the PROCESS, ACTIVITY, or TASK be completed to establish compliance with this standard.

This standard does not prescribe the name, format, or explicit content of the documentation to be produced. This standard requires documentation of TASKS, but the decision of how to package this documentation is left to the user of the standard.

This standard does not prescribe a specific life cycle model. The users of this standard are responsible for selecting a life cycle model for the software project and for mapping the PROCESSES, ACTIVITIES, and TASKS in this standard onto that model.

Annex A provides rationale for the clauses of this standard. Annex B provides guidance on the provisions of this standard.

For the purposes of this standard:

- “shall” means that compliance with a requirement is mandatory for compliance with this standard;
- “should” means that compliance with a requirement is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement;
- “establish” means to define, document, and implement; and
- where this standard uses the term “as appropriate” in conjunction with a required PROCESS, ACTIVITY, TASK or output, the intention is that the MANUFACTURER shall use the PROCESS, ACTIVITY, TASK or output unless the MANUFACTURER can document a justification for not so doing.

MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

1 Scope

1.1 * Purpose

This standard defines the life cycle requirements for MEDICAL DEVICE SOFTWARE. The set of PROCESSES, ACTIVITIES, and TASKS described in this standard establishes a common framework for MEDICAL DEVICE SOFTWARE life cycle PROCESSES.

1.2 * Field of application

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).

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.).

1.3 Relationship to other standards

This MEDICAL DEVICE SOFTWARE life cycle standard is to be used together with other appropriate standards when developing a MEDICAL DEVICE. Annex C shows the relationship between this standard and other relevant standards.

1.4 Compliance

Compliance with this standard is defined as implementing all of the PROCESSES, ACTIVITIES, and TASKS identified in this standard in accordance with the software safety class.

NOTE The software safety classes assigned to each requirement are identified in the normative text following the requirement.

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1 In preparation.

Compliance is determined by inspection of all documentation required by this standard including the RISK MANAGEMENT FILE, and assessment of the PROCESSES, ACTIVITIES and TASKS required for the software safety class. *deleted text*.

NOTE 1 This assessment could be carried out by internal or external audit.

NOTE 2 Although the specified PROCESSES, ACTIVITIES, and TASKS are performed, flexibility exists in the methods of implementing these PROCESSES and performing these ACTIVITIES and TASKS.

NOTE 3 Where any requirements contain "as appropriate" and were not performed, documentation for the justification is necessary for this assessment.

NOTE 4 The term "conformance" is used in ISO/IEC 12207 where the term "compliance" is used in this standard.

NOTE 5 For compliance of LEGACY SOFTWARE see 4.4.

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.

ISO 14971, *Medical devices – Application of risk management to medical devices*.

3 * Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
ACTIVITY
a set of one or more interrelated or interacting TASKS

3.2
ANOMALY
any condition that deviates from the expected based on requirements specifications, design documents, standards, etc. or from someone's perceptions or experiences. ANOMALIES may be found during, but not limited to, the review, test, analysis, compilation, or use of MEDICAL DEVICE SOFTWARE or applicable documentation

NOTE Based on IEEE 1044:1993, definition 3.1.

3.3
ARCHITECTURE
organizational structure of a SYSTEM or component

[IEEE 610.12:1990]

3.4
CHANGE REQUEST
a documented specification of a change to be made to a MEDICAL DEVICE SOFTWARE

3.5
CONFIGURATION ITEM
entity that can be uniquely identified at a given reference point

NOTE Based on ISO/IEC 12207:2008, 4.7.

3.6
DELIVERABLE
required result or output (includes documentation) of an ACTIVITY or TASK