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Programska oprema za medicinske aparate – Procesi v življenjskem ciklu programske opreme (IEC 62304:2006)

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

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Logiciels de dispositifs médicaux - Processus du cycle de vie du logiciel (CEI 62304:2006)

Medizingeräte-Software - Software-Lebenszyklus-Prozesse (IEC 62304:2006)

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CENELEC

European Committee for Electrotechnical Standardization
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Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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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– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2009-06-01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.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62304:2006 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:

IEC 60601-1-4 + A1	NOTE	Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 61508-3	NOTE	Harmonized as EN 61508-3:2001 (not modified).
IEC 61010-1	NOTE	Harmonized as EN 61010-1:2001 (not modified).
ISO 9000	NOTE	Harmonized as EN ISO 9000:2005 (not modified).
ISO 9001	NOTE	Harmonized as EN ISO 9001:2000 (not modified).
ISO 13485	NOTE	Harmonized as EN ISO 13485:2003 (not modified).
IEC 60601-1-6	NOTE	Harmonized as EN 60601-1-6:2004 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
ISO 14971	-[1)]	Medical devices - Application of risk management to medical devices	EN ISO 14971	2000[2)]

[1)] Undated reference.

[2)] Valid edition at date of issue.

IEC 62304

Edition 1.0 2006-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical device software – Software life cycle processes

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

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CONTENTS

FOREWORD 4
INTRODUCTION 6

1 Scope 9
1.1 * Purpose 9
1.2 * Field of application 9
1.3 Relationship to other standards 9
1.4 Compliance 9
2 * Normative references 10
3 * Terms and definitions 10
4 * General requirements 14
4.1 * Quality management system 14
4.2 * RISK MANAGEMENT 15
4.3 * Software safety classification 15
5 Software development PROCESS 16
5.1 * Software development planning 16
5.2 * Software requirements analysis 18
5.3 * Software ARCHITECTURAL design 20
5.4 * Software detailed design 21
5.5 * SOFTWARE UNIT implementation and verification 21
5.6 * Software integration and integration testing 22
5.7 * SOFTWARE SYSTEM testing 24
5.8 * Software release 25
6 Software maintenance PROCESS 26
6.1 * Establish software maintenance plan 26
6.2 * Problem and modification analysis 26
6.3 * Modification implementation 27
7 * Software RISK MANAGEMENT PROCESS 28
7.1 * Analysis of software contributing to hazardous situations 28
7.2 RISK CONTROL measures 29
7.3 VERIFICATION of RISK CONTROL measures 29
7.4 RISK MANAGEMENT of software changes 30
8 * Software configuration management PROCESS 30
8.1 * Configuration identification 30
8.2 * Change control 31
8.3 * Configuration status accounting 31
9 * Software problem resolution PROCESS 31
9.1 Prepare PROBLEM REPORTS 31
9.2 Investigate the problem 32
9.3 Advise relevant parties 32
9.4 Use change control process 32
9.5 Maintain records 32
9.6 Analyse problems for trends 32
9.7 Verify software problem resolution 33
9.8 Test documentation contents 33

Annex A (informative) Rationale for the requirements of this standard....34
Annex B (informative) Guidance on the provisions of this standard....37
Annex C (informative) Relationship to other standards....53
Annex D (informative) Implementation....74

Bibliography....76

Index of defined terms....77

Figure 1 – Overview of software development PROCESSES and ACTIVITIES....7
Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES....7
Figure B.1 – Example of partitioning of SOFTWARE ITEMS....42
Figure C.1 – Relationship of key MEDICAL DEVICE standards to IEC 62304....54
Figure C.2 – Software as part of the V-model....56
Figure C.3 – Application of IEC 62304 with IEC 61010-1....66

Table A.1 – Summary of requirements by software safety class....36
Table B.1 – Development (model) strategies as defined at ISO/IEC 12207....38
Table C.1 – Relationship to ISO 13485:2003....54
Table C.2 – Relationship to ISO 14971:2000....55
Table C.3 – Relationship to IEC 60601-1....58
Table C.4 – Relationship to IEC 60601-1-4....62
Table C.5 – Relationship to ISO/IEC 12207....68
Table D.1 – Checklist for small companies without a certified QMS....75

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

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 is further divided into a set of ACTIVITIES, with most ACTIVITIES further divided into 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 HAZARD is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. HAZARDS 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.

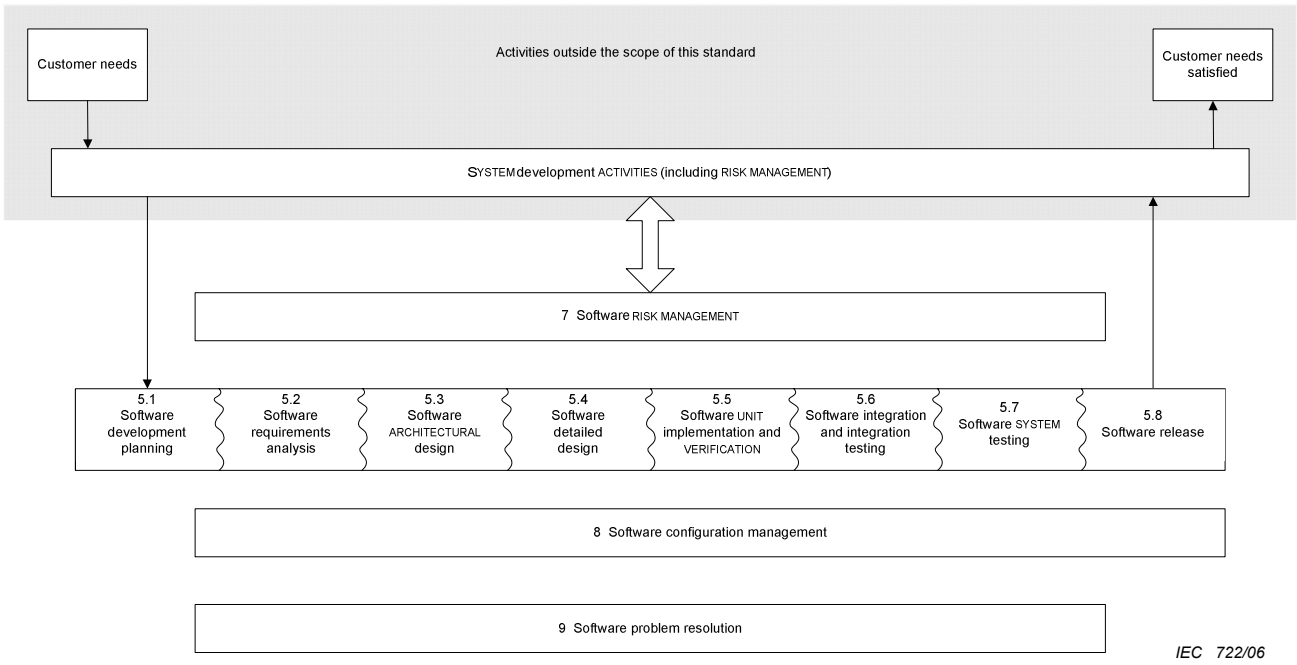

Figure 1 – Overview of software development PROCESSES and ACTIVITIES

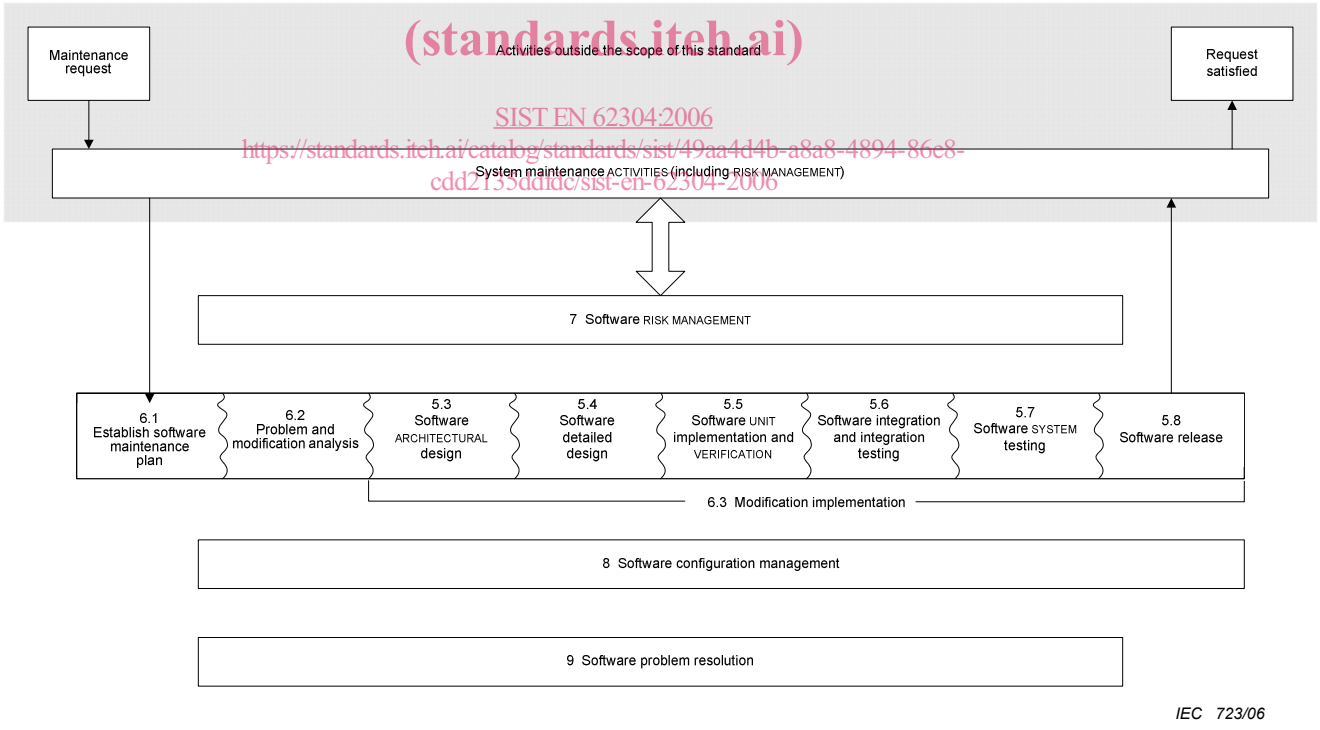

Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES

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).

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.

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.

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

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.

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. See Annex D.

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.