



IEC 62304

Edition 1.1 2015-06  
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD



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**Medical device software – Software life cycle processes**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

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# REDLINE VERSION



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## CONTENTS

FOREWORD .....	4
INTRODUCTION .....	6
<b>INTRODUCTION to Amendment 1 .....</b>	<b>8</b>
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 .....	15
4.1 * Quality management system .....	15
4.2 * RISK MANAGEMENT .....	16
4.3 * Software safety classification .....	16
<b>4.4 * LEGACY SOFTWARE .....</b>	<b>18</b>
5 Software development PROCESS .....	19
5.1 * Software development planning .....	19
5.2 * Software requirements analysis .....	21
5.3 * Software ARCHITECTURAL design .....	23
5.4 * Software detailed design .....	24
5.5 * SOFTWARE UNIT implementation <del>and verification</del> .....	25
5.6 * Software integration and integration testing .....	25
5.7 * SOFTWARE SYSTEM testing .....	27
5.8 * Software release .....	28
6 Software maintenance PROCESS .....	29
6.1 * Establish software maintenance plan .....	29
6.2 * Problem and modification analysis .....	30
6.3 * Modification implementation .....	31
7 * Software RISK MANAGEMENT PROCESS .....	31
7.1 * Analysis of software contributing to hazardous situations .....	31
7.2 RISK CONTROL measures .....	32
7.3 VERIFICATION of RISK CONTROL measures .....	32
7.4 RISK MANAGEMENT of software changes .....	33
8 * Software configuration management PROCESS .....	33
8.1 * Configuration identification .....	33
8.2 * Change control .....	33
8.3 * Configuration status accounting .....	34
9 * Software problem resolution PROCESS .....	34
9.1 Prepare PROBLEM REPORTS .....	34
9.2 Investigate the problem .....	35
9.3 Advise relevant parties .....	35
9.4 Use change control process .....	35
9.5 Maintain records .....	35
9.6 Analyse problems for trends .....	35
9.7 Verify software problem resolution .....	35

9.8 Test documentation contents .....	36
Annex A (informative) Rationale for the requirements of this standard .....	37
Annex B (informative) Guidance on the provisions of this standard .....	40
Annex C (informative) Relationship to other standards .....	58
Annex D (informative) Implementation .....	84
Bibliography .....	86
Index of defined terms .....	88
Figure 1 – Overview of software development PROCESSES and ACTIVITIES .....	7
Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES .....	7
Figure 3 – Assigning software safety classification .....	16
Figure B.2 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION, and HARM – from ISO 14971:2007 Annex E .....	44
Figure B.1 – Example of partitioning of SOFTWARE ITEMS .....	46
Figure C.1 – Relationship of key MEDICAL DEVICE standards to IEC 62304 .....	59
Figure C.2 – Software as part of the V-model .....	62
Figure C.3 – Application of IEC 62304 with IEC 61010-1 .....	72
Table A.1 – Summary of requirements by software safety class .....	39
Table B.1 – Development (model) strategies as defined in ISO/IEC 12207 .....	41
Table C.1 – Relationship to ISO 13485:2003 .....	60
Table C.2 – Relationship to ISO 14971:2000 2007 .....	61
Table C.3 – Relationship to IEC 60601-1 .....	64
<del>Table C.4 – Relationship to IEC 60601-4 .....</del>	<del>64</del>
Table C.5 – Relationship to ISO/IEC 12207 .....	74
Table D.1 – Checklist for small companies without a certified QMS .....	85

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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### MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

#### FOREWORD

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**In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through. A separate Final version with all changes accepted is available in this publication.**

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.

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 the base publication and its amendment will remain unchanged until the stability 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

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- 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.

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## INTRODUCTION

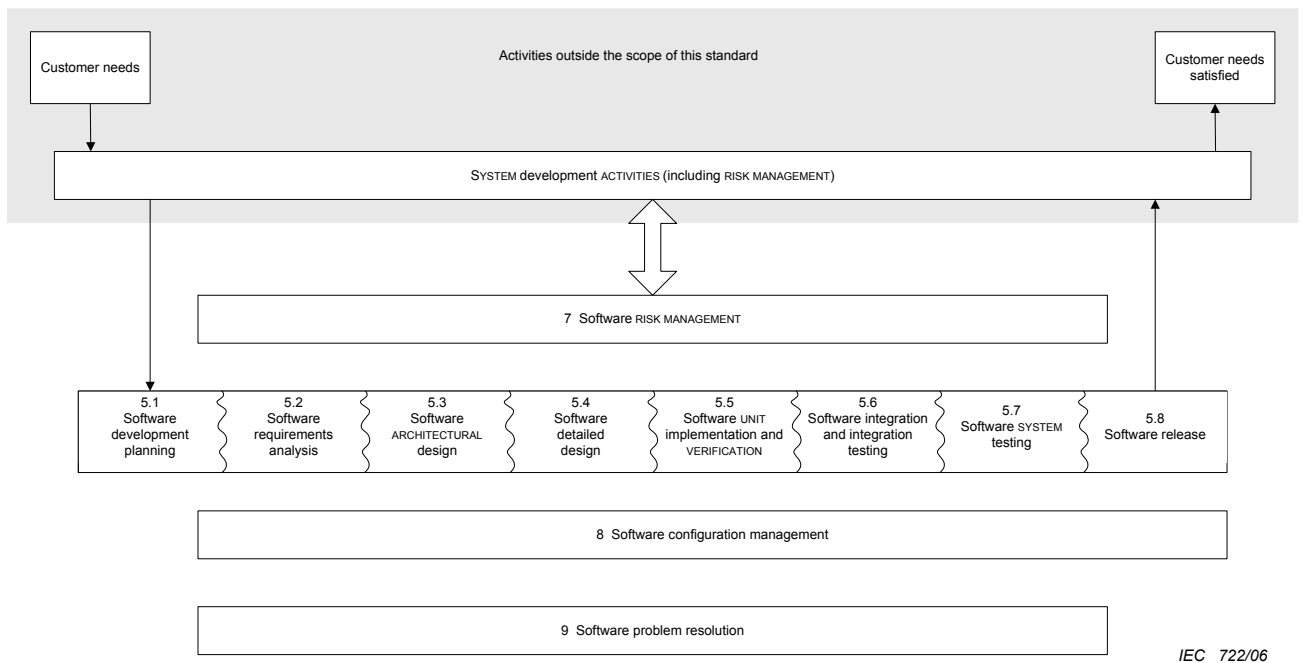
Software is often an integral part of MEDICAL DEVICE technology. Establishing the SAFETY and effectiveness of a MEDICAL DEVICE containing software requires knowledge of what the software is intended to do and demonstration that the use of the software fulfils those intentions without causing any unacceptable 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~~ consists of a set of ACTIVITIES, with most ACTIVITIES ~~further divided into~~ consisting of a set of TASKS.

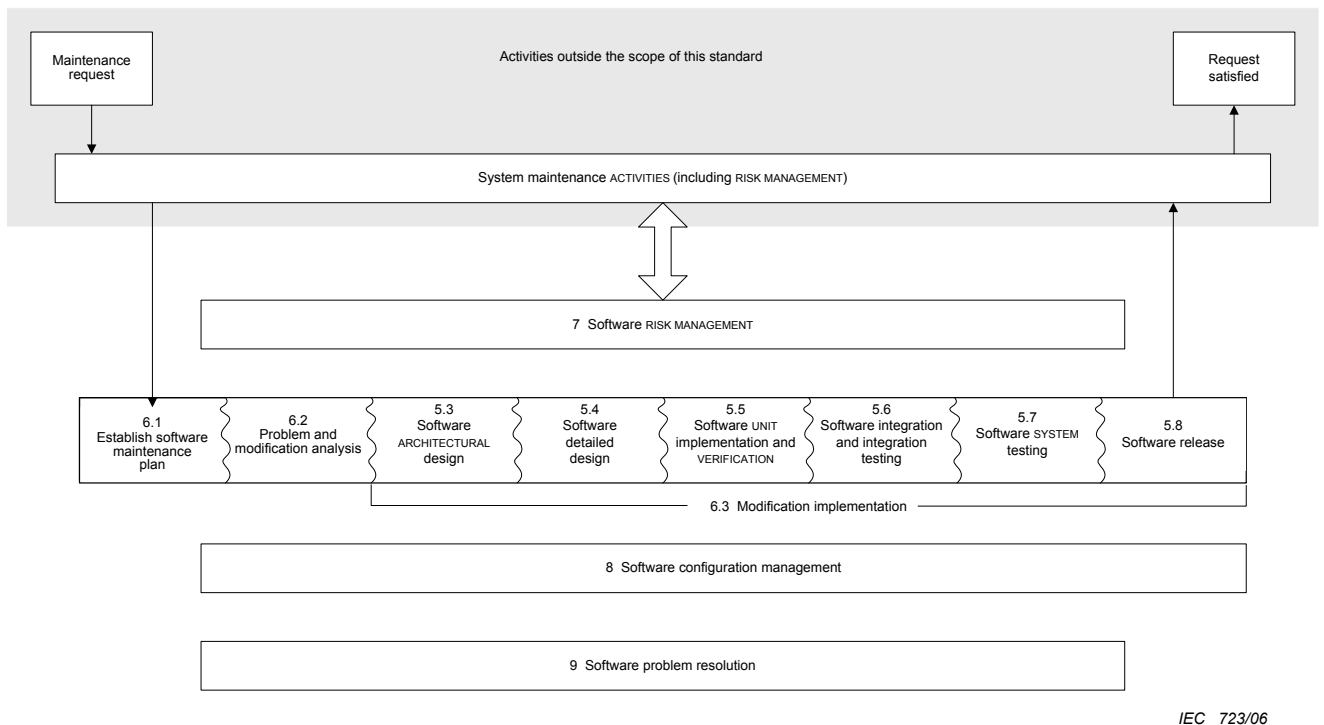
As a basic foundation it is assumed that MEDICAL DEVICE SOFTWARE is developed and maintained within a quality management system (see 4.1) and a RISK MANAGEMENT system (see 4.2). The RISK MANAGEMENT PROCESS is already very well addressed by the International Standard ISO 14971. Therefore IEC 62304 makes 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 ~~HAZARD~~ HAZARDOUS SITUATION is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. ~~HAZARDS~~ 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.

## INTRODUCTION to Amendment 1

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.

# 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.

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<sup>1</sup> [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.

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<sup>1</sup> In preparation.

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.

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.*



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## CONTENTS

FOREWORD .....	4
INTRODUCTION .....	6
INTRODUCTION to Amendment 1 .....	8
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 .....	15
4.1 * Quality management system .....	15
4.2 * RISK MANAGEMENT .....	15
4.3 * Software safety classification .....	16
4.4 * LEGACY SOFTWARE .....	17
5 Software development PROCESS .....	18
5.1 * Software development planning .....	18
5.2 * Software requirements analysis .....	21
5.3 * Software ARCHITECTURAL design .....	22
5.4 * Software detailed design .....	23
5.5 * SOFTWARE UNIT implementation .....	24
5.6 * Software integration and integration testing .....	25
5.7 * SOFTWARE SYSTEM testing .....	26
5.8 * Software release .....	27
6 Software maintenance PROCESS .....	28
6.1 * Establish software maintenance plan .....	28
6.2 * Problem and modification analysis .....	29
6.3 * Modification implementation .....	30
7 * Software RISK MANAGEMENT PROCESS .....	30
7.1 * Analysis of software contributing to hazardous situations .....	30
7.2 RISK CONTROL measures .....	31
7.3 VERIFICATION of RISK CONTROL measures .....	31
7.4 RISK MANAGEMENT of software changes .....	31
8 * Software configuration management PROCESS .....	32
8.1 * Configuration identification .....	32
8.2 * Change control .....	32
8.3 * Configuration status accounting .....	33
9 * Software problem resolution PROCESS .....	33
9.1 Prepare PROBLEM REPORTS .....	33
9.2 Investigate the problem .....	33
9.3 Advise relevant parties .....	33
9.4 Use change control process .....	34
9.5 Maintain records .....	34
9.6 Analyse problems for trends .....	34
9.7 Verify software problem resolution .....	34

9.8 Test documentation contents .....	34
Annex A (informative) Rationale for the requirements of this standard .....	35
Annex B (informative) Guidance on the provisions of this standard .....	38
Annex C (informative) Relationship to other standards .....	56
Annex D (informative) Implementation .....	75
Bibliography .....	77
Index of defined terms .....	79
Figure 1 – Overview of software development PROCESSES and ACTIVITIES .....	7
Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES .....	7
Figure 3 – Assigning software safety classification .....	16
Figure B.2 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION, and HARM – from ISO 14971:2007 Annex E .....	42
Figure B.1 – Example of partitioning of SOFTWARE ITEMS .....	44
Figure C.1 – Relationship of key MEDICAL DEVICE standards to IEC 62304 .....	56
Figure C.2 – Software as part of the V-model .....	59
Figure C.3 – Application of IEC 62304 with IEC 61010-1 .....	67
Table A.1 – Summary of requirements by software safety class .....	37
Table B.1 – Development (model) strategies as defined in ISO/IEC 12207 .....	39
Table C.1 – Relationship to ISO 13485:2003 .....	57
Table C.2 – Relationship to ISO 14971:2007 .....	58
Table C.3 – Relationship to IEC 60601-1 .....	61
Table C.5 – Relationship to ISO/IEC 12207 .....	69
Table D.1 – Checklist for small companies without a certified QMS .....	76

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## INTRODUCTION

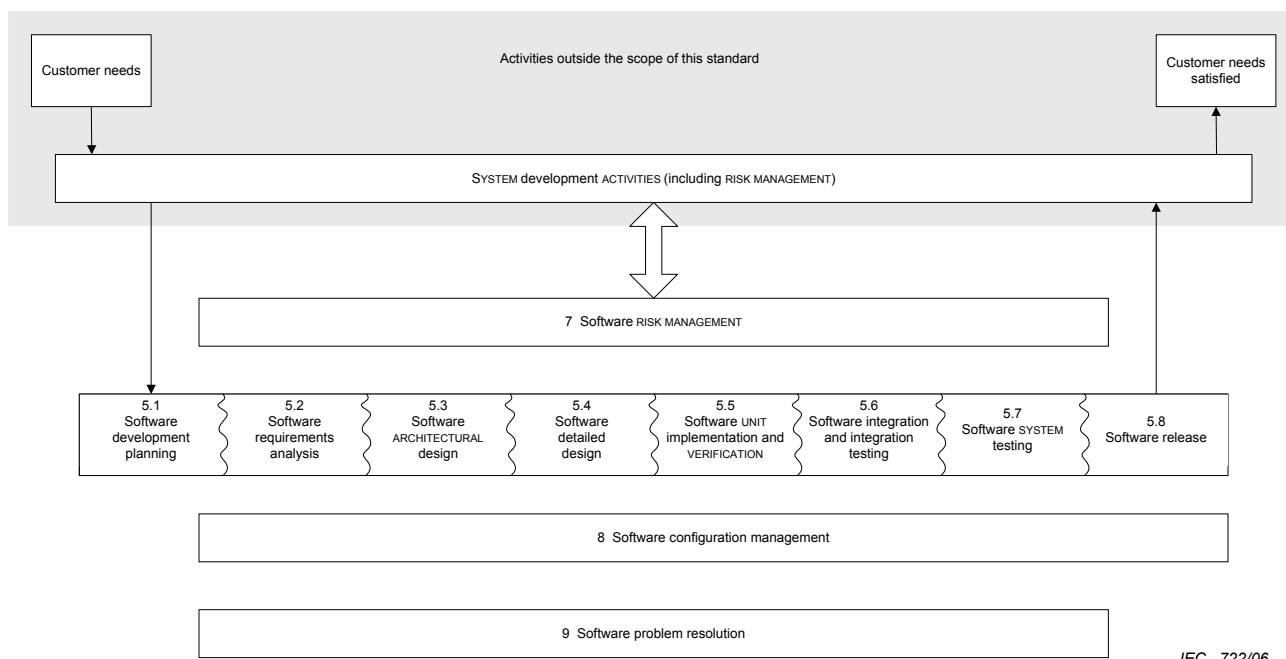
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This standard provides a framework of life cycle PROCESSES with ACTIVITIES and TASKS necessary for the safe design and maintenance of MEDICAL DEVICE SOFTWARE. This standard provides requirements for each life cycle PROCESS. Each life cycle PROCESS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

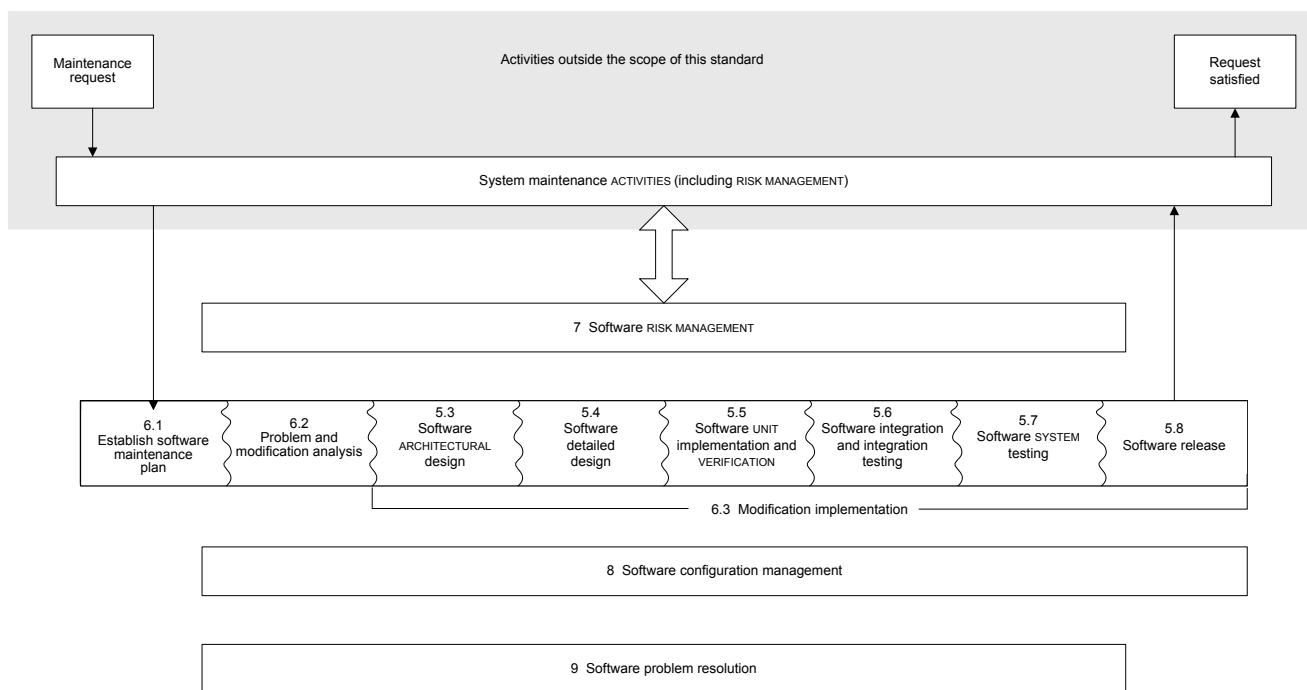
Whether software is a contributing factor to a HAZARDOUS SITUATION is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. HAZARDOUS SITUATIONS that could be indirectly caused by software (for example, by providing misleading information that could cause inappropriate 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.

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IEC 722/06

**Figure 1 – Overview of software development PROCESSES and ACTIVITIES**



IEC 723/06

**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

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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.

## INTRODUCTION to Amendment 1

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.

# 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<sup>1</sup> [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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<sup>1</sup> 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.

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*.