INTERNATIONAL STANDARD

IEC
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2006-05

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

*This **English-language** version is derived from the original **bilingual** publication by leaving out all French-language pages. Missing page numbers correspond to the French-language pages.*

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INTERNATIONAL ELECTROTECHNICAL COMMISSION
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MEDICAL DEVICE SOFTWARE –
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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- withdrawn;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.

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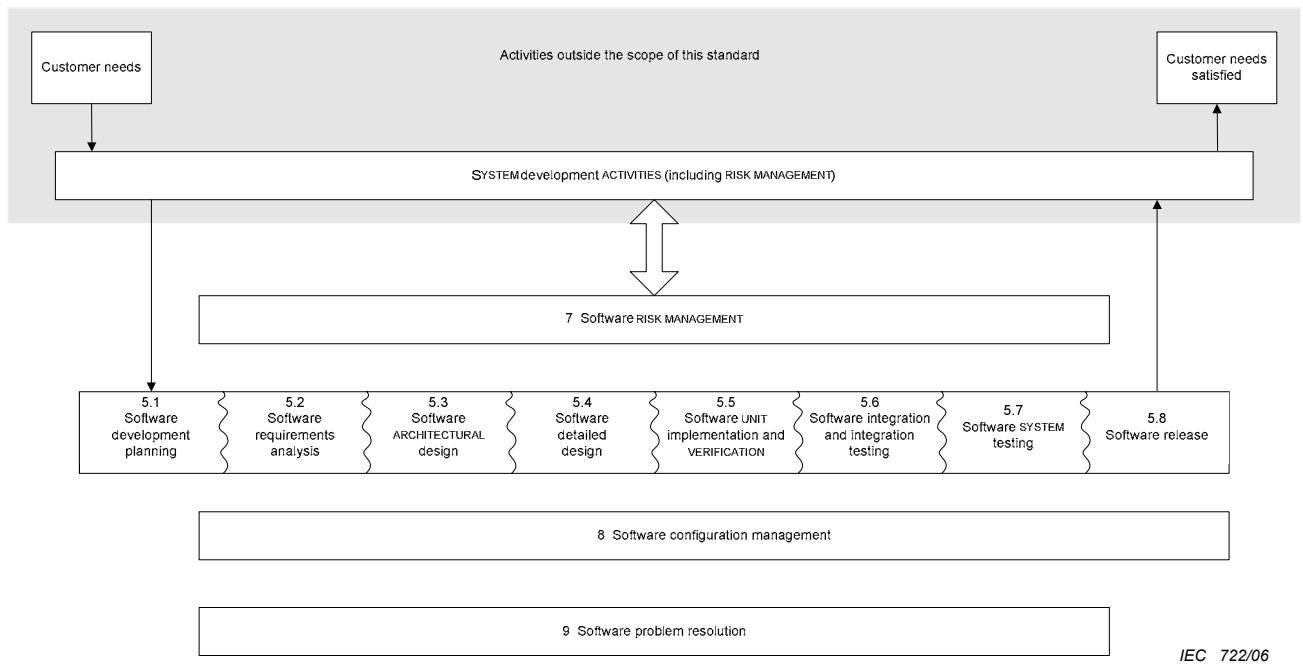
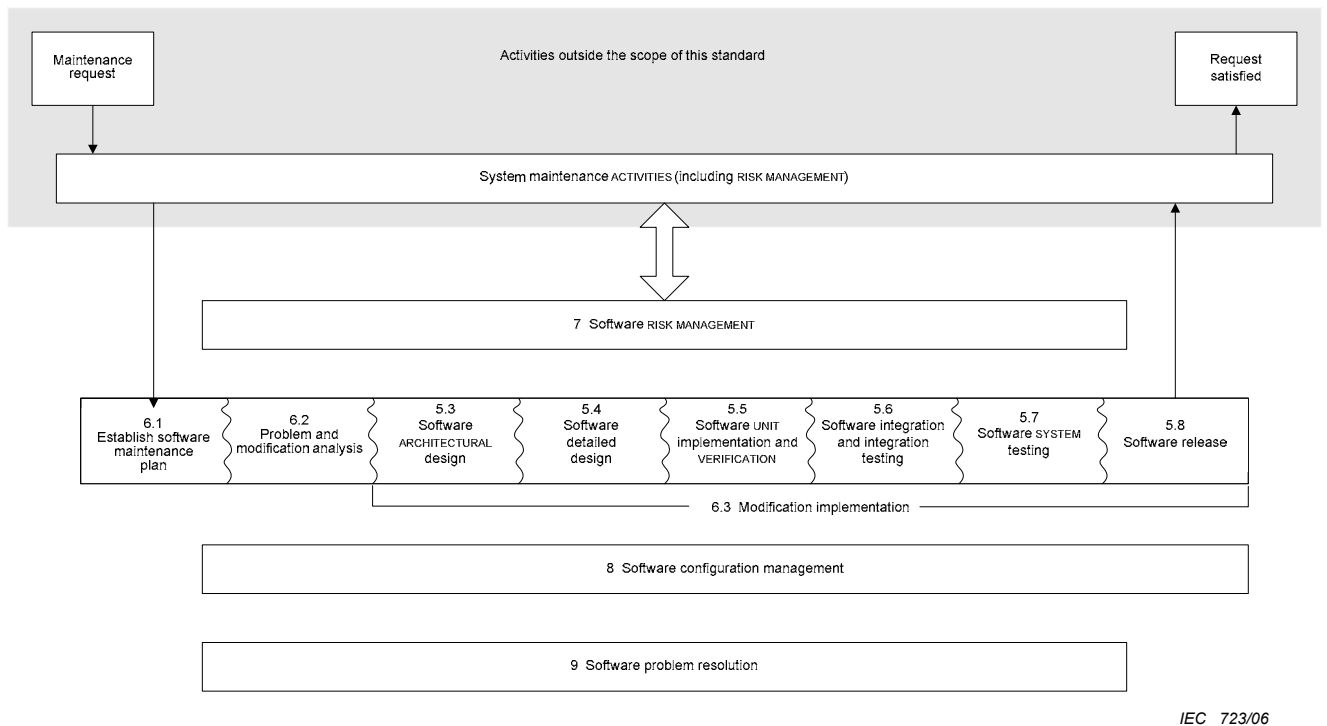**Figure 1 – Overview of software development PROCESSES and ACTIVITIES**

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.

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*.