

# TECHNICAL REPORT



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## Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software

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Part 1: Guidance on the application of ISO 14971 to medical device software**

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**MEDICAL DEVICE SOFTWARE –****Part 1: Guidance on the application of ISO 14971  
to medical device software**

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IEC 80002-1, which is a technical report, 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.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/639A/DTR	62A/664/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table. In ISO, the technical report has been approved by 16 P-members out of 17 having cast a vote.

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

In this technical report 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 TECHNICAL REPORT THAT HAVE BEEN DEFINED IN CLAUSE 2 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

A list of all parts of the IEC 80002 series, published under the general title *Medical device software*, can be found on the IEC website.

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- withdrawn,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.

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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 implementation of the software fulfils those intentions without causing any unacceptable RISKS.

It is important to understand that software is not itself a HAZARD, but software may contribute to HAZARDOUS SITUATIONS. Software should always be considered in a SYSTEM perspective and software RISK MANAGEMENT cannot be performed in isolation from the SYSTEM.

Complex software designs can permit complex sequences of events which may contribute to HAZARDOUS SITUATIONS. Much of the TASK of software RISK MANAGEMENT consists of identifying those sequences of events that can lead to a HAZARDOUS SITUATION and identifying points in the sequences of events at which the sequence can be interrupted, preventing HARM or reducing its probability.

Software sequences of events which contribute to HAZARDOUS SITUATIONS may fall into two categories:

- a) sequences of events representing unforeseen software responses to inputs (errors in specification of the software);
- b) sequences of events arising from incorrect coding (errors in implementation of the software).

These categories are specific to software, arising from the difficulty of correctly specifying and implementing a complex SYSTEM and the difficulty of completely verifying a complex SYSTEM.

Since it is very difficult to estimate the probability of software ANOMALIES that could contribute to HAZARDOUS SITUATIONS, and since software does not fail randomly in use due to wear and tear, the focus of software aspects of RISK ANALYSIS should be on identification of potential software functionality and ANOMALIES that could result in HAZARDOUS SITUATIONS – not on estimating probability. RISKS arising from software ANOMALIES need most often to be evaluated on the SEVERITY of the HARM alone.

RISK MANAGEMENT is always a challenge and becomes even more challenging when software is involved. The following clauses contain additional details regarding the specifics of software and provide guidance for understanding ISO 14971:2007 in a software perspective.

- **Organization of the technical report**

This technical report is organized to follow the structure of ISO 14971:2007 and guidance is provided for each RISK MANAGEMENT activity in relation to software.

There is some intentional REDUNDANCY in the information provided due to the iterative nature of RISK MANAGEMENT activities in the software LIFE-CYCLE.