

INTERNATIONAL STANDARD

**Medical device software –
Part 3: Process reference model of medical device software life cycle processes
(IEC 62304)**



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2014 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue

The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 14 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

More than 55 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.



INTERNATIONAL STANDARD

Medical device software –

**Part 3: Process reference model of medical device software life cycle processes
(IEC 62304)**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE

ICS 11.040.01

ISBN 978-2-8322-1616-3

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
0.1 Background	5
0.2 Organization of this technical report	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Medical device software life cycle processes	7
4.1 Software development process	7
4.1.1 Software development planning	7
4.1.2 Software requirements analysis	8
4.1.3 Software architectural design.....	8
4.1.4 Software detailed design	9
4.1.5 Software unit implementation and verification	9
4.1.6 Software integration and integration testing	10
4.1.7 Software system testing.....	10
4.1.8 Software release	11
4.2 Software maintenance	11
4.2.1 Purpose.....	11
4.2.2 Outcomes	11
4.3 Software risk management.....	12
4.3.1 Purpose.....	12
4.3.2 Outcomes	12
4.4 Software configuration management	13
4.4.1 Purpose.....	13
4.4.2 Outcomes	13
4.5 Software problem resolution.....	14
4.5.1 Purpose.....	14
4.5.2 Outcomes	14
Annex A (informative) Development of this technical report	16
Annex B (informative) Mapping between IEC 62304:2006 and ISO/IEC 12207:2008	18
Bibliography.....	28
Figure A.1 – Requirements in process elements of IEC 62304:2006 and ISO/IEC 12207:2008	16
Figure A.2 – Development of process outcomes for medical device software development PRM	17
Table A.1 – Direct process mappings between IEC 62304:2006 and ISO/IEC 12207:2008	17
Table B.1 – Mapping between process outcomes of the PRM and the requirements of IEC 62304:2006, including their safety classes, and the requirements of ISO/IEC 12207:2008 (1 of 9).....	19

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICE SOFTWARE –**Part 3: Process reference model of medical
device software life cycle processes (IEC 62304)**

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC TR 80002-3, 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. It is published as a double logo standard.

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

Enquiry draft	Report on voting
62A/918/DTR	62A/928/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 14 P members out of 16 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2 and in accordance with ISO/IEC 24774, *Systems and software engineering – Life cycle management – Guidelines for process description*.

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 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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

0.1 Background

Software is often an integral part of medical device technology. Establishing the safety and effectiveness of a medical device containing software requires well designed software that fulfils its purpose without causing any unacceptable risks. Following an internationally approved set of software development practices provides one way of achieving this.

This technical report (TR) provides a framework of life cycle processes supporting the safe design and maintenance of medical device software called the process reference model (PRM). The process descriptions in this PRM are fully compliant with the requirements of ISO/IEC 24774:2010, *Systems and software engineering – Life cycle management – Guidelines for process description*.

This TR presents the PRM for medical device software development as a result of integrating requirements from IEC 62304:2006 and from the international standard of software life-cycle processes ISO/IEC 12207:2008.

This TR is aimed at medical device software developers who can use it for realizing the set of requirements they have to achieve to be compliant with IEC 62304:2006 in the scope of the safety class of the medical device software they are developing. Each process outcome with a corresponding safety class is a requirement in IEC 62304:2006. The process outcomes without a corresponding safety class are based only on ISO/IEC 12207:2008. These process outcomes provide additions that are beneficial when achieving the purpose of the process and could be regarded as a valuable contribution to safety-critical software development. The PRM may also be used to provide a common basis for different models and methods for process assessment, ensuring that the results of the assessments can be reported in a common context. Assessors who are concerned with examining medical device software processes can use the PRM as an agreed list of IEC 62304 process outcomes to inform audit check listing and reporting.

The process descriptions in the PRM incorporate a statement of the purpose of the process which describes at a high level the overall objectives of performing the process, together with the set of outcomes which demonstrate the successful achievement of the process purpose. These process outcomes are the software life cycle process requirements – the statements of the overall goal of performing the process. In any process description, the set of process outcomes are necessary and sufficient to achieve the purpose of the process.

A manufacturer of a medical device software system is required to assign a software safety class (A, B, or C) according to the possible effects on the patient, operator, or other people resulting from a hazard to which the software system contributes, described in greater detail in IEC 62304:2006. The software safety classes are assigned based on severity as follows:

- Class A: no injury or damage to health is possible;
- Class B: non-serious injury is possible;
- Class C: death or serious injury is possible.

0.2 Organization of this technical report

This TR is organized to follow the structure of IEC 62304. Annex A describes the development of the TR in greater detail. Annex B provides a mapping from IEC 62304 clauses together with their safety classes to the corresponding ISO/IEC 12207:2008 processes. The life cycle processes of the PRM for medical device software development are described in terms of process name, process purpose and the corresponding process outcomes. The outcomes marked with an “[ISO/IEC 12207]” at the end of the outcome statement are derived from ISO/IEC 12207:2008, with no directly corresponding requirement in IEC 62304. Users of this PRM who wish to examine only the IEC 62304 requirements can elect to disregard the outcomes that are based only on ISO/IEC 12207:2008.

MEDICAL DEVICE SOFTWARE –

Part 3: Process reference model of medical device software life cycle processes (IEC 62304)

1 Scope

This part of IEC 80002, which is a technical report (TR), provides the description of software life cycle processes for medical devices. The medical device software life cycle processes are derived from IEC 62304:2006, with corresponding safety classes. They have been aligned with the software development life cycle processes of ISO/IEC 12207:2008 and are presented herein in full compliance with ISO/IEC 24774:2010. The content of these three standards provides the foundation of this TR.

This TR does not address:

- areas already covered by existing related standards, e.g. the international standards that relate to the four standards used to build this TR (see Bibliography);
- FDA guidance documents; or
- software development tools.

This TR describes the PRM for medical device software development and is limited in scope to the life cycle processes described in IEC 62304:2006. The process names correspond to those of IEC 62304:2006. The mappings provided in Annex B are essential for the alignment between IEC 62304:2006 (which is based on ISO/IEC 12207:1995) and ISO/IEC 12207:2008, developed to address the detailed normative relationship between the two standards.

This technical report is not intended to be used as the basis of regulatory inspection or certification assessment activities.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 62304:2006, *Medical device software – Software life cycle processes*

ISO/IEC 12207:2008, *Systems and software engineering – Software life cycle processes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 62304:2006 apply.

NOTE To be consistent with the requirements for developing a PRM, the guidelines set forth in ISO/IEC 24774 were followed. Having a dedicated software risk management process enables the software developers to realize the set of requirements they have to adhere to when developing software for medical devices. This PRM also enables the medical device software developers to determine the requirements necessary to develop software for a specific safety class. The PRM presented in this TR includes only the software risk management requirements of ISO 14971 that are a part of IEC 62304. The software risk management terminology is therefore derived directly from ISO 14971. For the purposes of this TR, the software development-related terms and definitions used are inherited from IEC 62304.