

Technical Information Report

AAMI/IEC TIR80002-3: 2016

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

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

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Abstract: 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.

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Glossary of equivalent standards

International Standards or Technical Reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

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Committee representation

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Software Working Group

The publication of AAMI/IEC TIR80002-3:2016 as a new American Technical Report was initiated by the AAMI Software Working Group, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Software Working Group (U.S. Sub-TAG for ISO/TC 210/JWG 02), chaired by Sherman Eagles of SoftwareCPR and John Murray of FDA/CDRH, played an active part in developing IEC 80002-3.

At the time this document was published, the **AAMI Software Working Group** had the following members:

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Background of AAMI/IEC TIR80002-3:2016

As indicated in the foreword to the main body of this document (page ix), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this technical report, which was developed by a joint ISO and International Electrotechnical Commission (IEC) working group, ISO/TC 210-IEC/SC 62A/JWG2, Medical Device Software.

U.S. participation in ISO/TC 210-IEC/SC 62A/JWG2 is organized through the U.S. sub-Technical Advisory Group to ISO/TC 210-IEC/SC 62A/JWG2, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the technical report. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the technical report. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

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Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr, Suite 301, Arlington, VA 22203-1633.

Foreword

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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*.

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