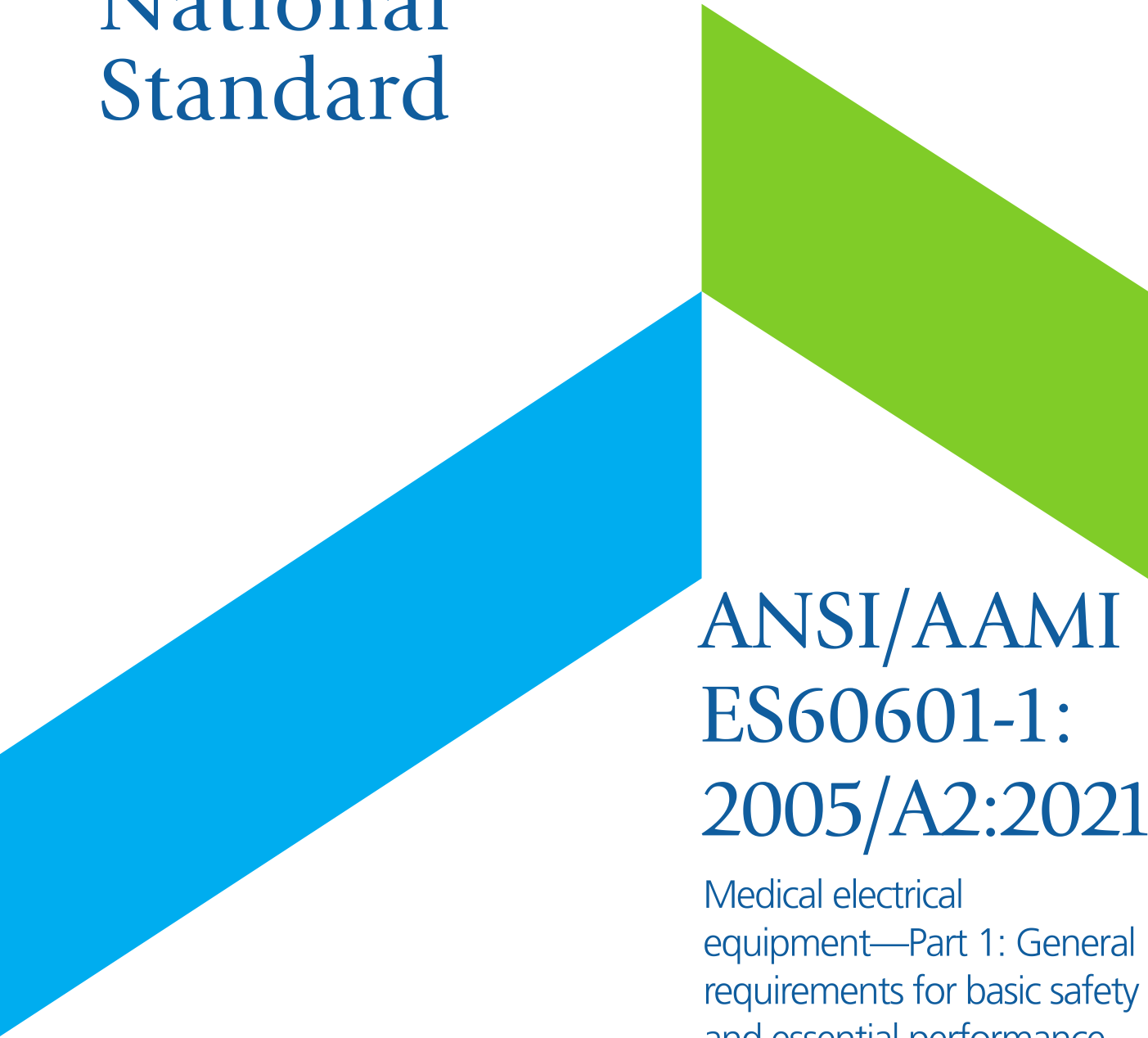


American National Standard



ANSI/AAMI ES60601-1: 2005/A2:2021

Medical electrical
equipment—Part 1: General
requirements for basic safety
and essential performance—
Amendment 2

Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, Amendment 2

Approved 07 January 2022 by
AAMI

Approved 01 February 2022 by
American National Standards Institute, Inc.

Abstract: This second amendment addresses changes to terminology and references since the main document was finalized in 2005 and first amended in 2012. There are additional updates to clauses to keep current with technology as well as to address questions received since the first amendment was published. The main document and amendments provide requirements for the safety and essential performance for all medical electrical equipment.

Keywords: medical electrical equipment, medical electrical systems, safety, essential performance

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Committee representation

Association for the Advancement of Medical Instrumentation

Electrical Safety Committee

The adoption of Amendment 2 to IEC 60601-1:2005 as an American National Standard was initiated by the AAMI Electrical Safety Committee. AAMI Electrical Safety Committee provides input to the U.S. TAG for IEC/SC 62A which is the responsible group for providing the U.S. input to the relevant group in IEC. U.S. representatives from AAMI Electrical Safety Committee and the TAG played an active part in developing the IEC document.

At the time this document was published, the **AAMI Electrical Safety Committee** has the following members:

Cochairs: Jeffrey L. Eggleston
Alex Grob

Members: Alan S. Berson, Bioresearch Funding Group
Stephen Briol, Nonin Medical Inc
Michael Britko, Draeger Medical Systems Inc
Steve Cantwell, Spacelabs Healthcare
Gregory Chase, TUV Rheinland of North America Inc
Martin Joseph Crnkovich, Fresenius Medical Care
Rebecca K. Crossley, UPMC Montefiore
Roberto Del Cid, Arthrex Inc
Yadin David, Biomedical Engineering Consultants LLC
Jeffrey L. Eggleston, Medtronic - Boulder
Leonard Eisner, Eisner Safety Consultants
Hamed Ghods, FDA - CDRH
Johanna Goforth, Eurofins E&E North America (MET Labs)
David L. Green, Square One Industries LLC
Alex Grob, MECA - Medical Equipment Compliance Associates LLC
Pamela Gwynn, UL LLC
Nabeel Jadeed, Ethicon Endo-Surgery
James Kamke, Baxter Healthcare Corporation
Kevin Van Kammen, ICU Medical Inc
Bahram Kevin Kayvani, Medline Industries, Inc
Brian Killoran, Hillrom, Inc
Alan Lipschultz, HealthCare Technology Consulting LLC
Martin Masters, Boston Scientific Corporation
Enio Montenegro, Cadwell Laboratories Inc
Robert Moore, ResMed Ltd
Susumu Nozawa, Siemens Healthineers
Nate Osborn, Stryker Instruments Division
Robert David G. Osborn, Philips
Brodie C. Pedersen, Borderless Compliance LLC
Salman Raza, Razalution Bureau LLC
Peter Rech, Smiths Medical
Steven Rus, STERIS Corporation | Healthcare
Robert Steurer, Steurer Consulting Group
Mark Swanson, Quality and Regulatory Expert Partners
Matthew Trachtenberg, Becton Dickinson & Company
Daidi Zhong, Chongqing University

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Essam El-Nady, Amgen Inc
Matthew English, TUV Rheinland of North America Inc
Gabriel Frederito, Boston Scientific Corporation
Joshua Kim, Hillrom, Inc
Travis J. Lindahl, Stryker Instruments Division
Yaqing Liu, Intertek
Richard Markle, Philips

Avital Merl, Becton Dickinson & Company
Behnam Molavi, Spacelabs Healthcare
David McCall, STERIS Corporation | Healthcare
James Shults, ICU Medical Inc
Sandy Weininger, FDA - CDRH
John Zekic, ResMed Ltd
Nicole Zuk, Siemens Medical Systems - Malvern, PA

NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of Amendment 2 to IEC 60601-1:2005 (ES60601-1)

As indicated in the foreword to the main body of this document (page v), 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 standard, which was developed by IEC/SC 62A to publish a second Amendment to IEC 60601-1, which updates references and other information to remain relevant and up to date.

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

AAMI encourages its committees to harmonize their work with International Standards in the area of safety and essential performance for medical electrical equipment. Upon review of IEC 60601-1:2005/A1:2012/A2:2020, the U.S. TAG for IEC/SC 62A and the AAMI Electrical Safety Committee decided to adopt it verbatim, as an Amendment to ANSI/AAMI ES60601-1.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “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 standard. “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.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an IEC document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g., colour instead of color);
- Use of SI units (e.g., metres instead of feet, Celsius instead of Fahrenheit, etc.);
- Decimal comma instead of a decimal point (e.g., 1 000,15 instead of 1,000.15).

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE Beginning with the IEC foreword on page ix, this American National Standard is identical to IEC 60601-1:2005/A1:2012/A2:2020.

Foreword

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/1389/FDIS	62A/1404/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base 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.

NOTE The attention of the users of this document 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

Introduction to Amendment 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

Introduction

Add, after the existing last paragraph, the following paragraph:

Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document.

1.3 * Collateral standards

Replace the existing second paragraph with:

Applicable collateral standards shall apply together with this standard.

Delete the existing third paragraph.

1.4 * Particular standards

Replace the existing first paragraph with:

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in this standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration.

Replace the existing second paragraph with:

A requirement of a particular standard takes priority over this standard and applicable collateral standards.

2 * Normative references

Replace the existing second paragraph with:

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, shall apply together with this standard when applicable. They shall be considered as being included among the normative references below. See 1.3.

Replace the following existing references to IEC 60601-1-2, IEC 60601-1-3 modified by Amendment 1, IEC 60601-1-6 and IEC 60601-1-8 by the following new references:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*
Amendment 1:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013
Amendment 2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Amendment 1:2012

Amendment 2:2020

Add the following new reference to the list:

IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers*

Replace, in the existing reference to IEC 60825-1, "2007" with "2014".

Replace the existing references to IEC 60950-1 and IEC 62304 by the following new references:

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*

Amendment 1:2009

Amendment 2:2013

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

Amendment 1:2015

Add the following normative references to the existing list:

IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

Replace the existing references to ISO 7000-DB:2004 by the following new reference:

ISO 7000, Graphical symbols for use on equipment

Replace, in the existing reference to ISO 7010, "2011" with "2019".

Replace, in the existing reference to ISO 14971, "2007" with "2019".

Replace, in the existing reference to ISO 15223-1, "2012" with "2016".

3 * Terminology and definitions

3.38

*** HARM**

Replace the existing term and definition, modified by Amendment 1, with:

3.38

*** HARM**

injury or damage to the health of people or animals, or damage to property or the environment

[SOURCE: ISO 14971:2019, definition 3.3, modified – "Or animals" added to the definition.]

3.39

HAZARD

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.4]

3.40

* HAZARDOUS SITUATION

Replace the existing term and definition, modified by Amendment 1, with:

3.40

* HAZARDOUS SITUATION

circumstance in which people, property, or the environment is/are exposed to one or more HAZARDS

[SOURCE: ISO 14971:2019, definition 3.5, modified – Note 1 to entry deleted.]

3.44

INTENDED USE

INTENDED PURPOSE

Replace the existing term and definition, modified by Amendment 1, with:

3.44

INTENDED USE

INTENDED PURPOSE

use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

Note to entry 1: The intended medical indication, PATIENT population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the INTENDED USE.

Note to entry 2: INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[SOURCE: ISO 14971:2019, definition 3.6, modified – Note 2 added.]

3.55

MANUFACTURER

Replace the existing term and definition, modified by Amendment 1, with:

3.55

MANUFACTURER

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person himself or on his behalf by another person(s)

Note to entry 1: ISO 13485 [30] defines “labelling” as “label, instructions for use, and any other information that is related to identification, technical description, INTENDED PURPOSE and proper use of the ME EQUIPMENT or ME SYSTEM, but excluding shipping documents”.

Note to entry 2: “Adapting” includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

Note to entry 3: In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

Note to entry 4: Adapted from ISO 14971:2019, definition 3.9.

3.72

OBJECTIVE EVIDENCE

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.11]

3.88

PROCEDURE

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.13, modified – Note 1 to entry deleted.]

3.89

PROCESS

Replace the existing term and definition, modified by Amendment 1, with:

3.89

PROCESS

set of interrelated or interacting activities that use inputs to deliver an intended result

Note to entry 1: Whether the “intended result” of a process is called output, product or service depends on the context of the reference.

Note to entry 2: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note to entry 3: Two or more interrelated and interacting processes in series can also be referred to as a process.

[SOURCE: ISO 14971:2019, definition 3.14]

3.98

RECORD

Add the following NOTES and replace the existing source statement for definition, modified by Amendment 1, with:

Note to entry 1: RECORDS can be used, for example, to formalize traceability and to provide evidence of VERIFICATION, preventive action and corrective action.

Note to entry 2: Generally RECORDS need not be under revision control.

[SOURCE: ISO 14971:2019, definition 3.16]

3.100

RESIDUAL RISK

Replace the existing term and definition, modified by Amendment 1, with:

3.100

RESIDUAL RISK

RISK remaining after RISK CONTROL measures have been implemented

[SOURCE: ISO 14971:2019, definition 3.17]

3.102

RISK

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.18]

3.103

RISK ANALYSIS

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.19]

3.104

RISK ASSESSMENT

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.20]

3.105

RISK CONTROL

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.21]

3.106

RISK EVALUATION

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.23]

3.107

RISK MANAGEMENT

Replace the existing term and definition, modified by Amendment 1, with:

3.107

RISK MANAGEMENT

systematic application of management policies, PROCEDURES and practices to the tasks of analysing, evaluating, controlling and monitoring RISK

Note to entry: For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

[SOURCE: ISO 14971:2019, definition 3.24, modified – NOTE added.]

3.108

RISK MANAGEMENT FILE

Replace the existing NOTE and source statement for definition, modified by Amendment 1, with:

Note to entry: All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

[SOURCE: ISO 14971:2019, definition 3.25, modified – NOTE added.]

3.114

SEVERITY

Replace the existing source statement for definition, modified by Amendment 1, with:

[SOURCE: ISO 14971:2019, definition 3.27]

3.136

USABILITY

Replace the existing term and definition, modified by Amendment 1, with: