

Technical Information Report

ANSI/AAMI/ ISO TIR 19218-1:2011 & A1:2013

Medical devices —
Hierarchal coding structure
for adverse events —
Part 1: Event-type codes

Medical devices — Hierarchal coding structure for adverse events — Part 1: Event-type codes

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Abstract: This technical information report specifies requirements for a coding structure for describing adverse events relating to medical devices. This edition incorporates a hierarchical structure, expanding on the adverse event type and cause/effect structure and relevant codes previously developed, to provide more specific details.

Keywords: adverse event reporting, coding

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, “(R)20xx” indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2008	ANSI/AAMI/IEC 60601-2-16:2008	Identical
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC 62366:2007	ANSI/AAMI/IEC 62366:2007	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2006 (2006-08-01 corrected)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11663:2009	Identical
ISO 11737-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO/TS 12417:2011	ANSI/AAMI/ISO TIR12417:2011	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 13958:2009	ANSI/AAMI/ISO 13958:2009	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959:2009	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007/(R)2010	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006/(R)2010	Identical
ISO/TS 19218-1:2011	ANSI/AAMI/ISO TIR19218:2011	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO/TR 22442-4:2010	ANSI/AAMI/ISO TIR22442-4:2010	Identical
ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee

The adoption of ISO Technical Specification (TS) 19218-1:2011 as an AAMI Technical Information Report was initiated by the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee, 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 Symbols and Nomenclature for Medical Devices Working Group (U.S. Sub-TAG for ISO/TC 210/WG 3), chaired by Leighton W. Hansel of Abbott Laboratories and Charles B. Sidebottom, PE of Medtronic, Inc., played an active part in developing the ISO Technical Specification.

At the time this document was published, the **AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee** had the following members:

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

Background of ANSI/AAMI adoption of ISO/TS 19218-1:2011

As indicated in the foreword to the main body of this document (page ix), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this technical specification.

International Technical Specification 19218-1 was developed by Working Group (WG) 3 Symbols and Nomenclature for Medical Devices, of ISO Technical Committee (TC) 210, Quality management and corresponding general aspects for medical devices, to specify requirements for a coding structure for use in reporting adverse events related to medical devices.

U.S. participation in this ISO/TC 210/WG 3 is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). AAMI administers the International Secretariat for ISO/TC 210 on behalf of the United States, and U.S. experts made a considerable contribution to this technical specification.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of ISO/TS 19218-1, the Quality Management and Corresponding General Aspects for Medical Devices Committee and the AAMI Symbols and Nomenclature for Medical Devices Working Group decided to adopt ISO/TS 19218-1:2011 verbatim as an AAMI Technical Information Report.

This edition incorporates a hierarchical structure, expanding on the adverse event type and cause/effect structure and relevant codes previously developed, to provide more specific details.

AAMI (and ANSI) have adopted other ISO documents. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this technical information report should not be considered inflexible or static. This technical information report, 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.

As used within the context of this document, “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 specification. “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.

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

NOTE— Beginning with the foreword on page ix, this AAMI TIR is identical to ISO/TS 19218-1:2011.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 19218-1 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This first edition of ISO/TS 19218-1, together with ISO/TS 19218-2, cancels and replaces ISO/TS 19218:2005, which has been technically revised.

ISO/TS 19218 consists of the following parts, under the general title *Medical devices — Hierarchical coding structure for adverse events*:

- *Part 1: Event-type codes*

The following part is under preparation:

- *Part 2: Evaluation codes*

Introduction

The adverse-event coding system specified in this part of ISO/TS 19218 envisages that medical device adverse-event reporting will originate from one of two sources: either the user or the manufacturer of the device concerned. In this context, users can be health care providers, but can also be the general public. This part of ISO/TS 19218 provides a structure by which an adverse-event type can be used to collect medical device surveillance information in the post-market phase. It also enables this information to be easily exchanged on an international basis using the common codes.

This part of ISO/TS 19218 can be used by the users, manufacturers and regulatory authorities in the following ways:

- users can report, to a manufacturer or a regulatory body, a code number to describe an adverse event that will be universally understood;
- manufacturers and regulatory authorities can easily recognize universally understood adverse-event types, which can be globally recognized by regulatory authorities;
- in addition, both users and manufacturers can apply these codes as part of a medical device surveillance or reporting system.

Medical devices — Hierarchical coding structure for adverse events — Part 1: Event-type codes

1 Scope

This part of ISO/TS 19218 specifies requirements for a hierarchical coding structure for describing adverse events relating to medical devices. The codes are intended for use by medical device users, manufacturers, regulatory authorities, health care facilities and other organizations. The codes can be used for coding events that are not related to death or serious injury, or malfunctions that could lead to death or serious injury.

This part of ISO/TS 19218 is not intended to be used to decide whether an incident is reportable or not.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

adverse event

event associated with a medical device that led to death or serious injury of a patient, user or other person, or that might lead to death or serious injury of a patient, user or other person if the event recurs

NOTE 1 This definition is consistent with guidance in GHTF/SG2/N54/R8:2006^[7].

NOTE 2 This definition includes malfunction or deterioration of a device which has not yet caused death or serious injury, but which could lead to death or serious injury.

2.2

serious injury

serious deterioration in a state of health that constitutes either a life-threatening illness or injury, or a permanent impairment of a body function or permanent damage to a body structure, or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

NOTE 1 The term “permanent” means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage.

NOTE 2 This definition is consistent with guidance in GHTF/SG2/N21/R8:1999^[5].

2.3

intended use

intended purpose

objective intent of the manufacturer regarding the use of a product, as reflected in the specifications, instructions or information provided by the manufacturer

NOTE This definition is consistent with GHTF/SG1/N41/R9:2005^[4].

3 Adverse-event-type code requirements

The adverse-event-type code characterizes the observed use/malfunction/failure of the medical device at the time the event occurred. The code shall be a four-digit numerical code selected from Table 1.

NOTE 1 The single code that most closely describes the adverse event can be used. However, multiple codes can sometimes be necessary to fully describe an adverse event.

NOTE 2 The adverse-event-type code can be useful in describing the hazard presented by an adverse event. It can also be useful in “user reporting systems”. When combined with the adverse-event evaluation code (from ISO/TS 19218-2), the adverse event is better characterized.

NOTE 3 The adverse-event-type codes chosen to describe the adverse event at the time of the event reflect the most up-to-date assessment of the adverse event and can take into account any additional information learned between occurrence of the event and submission of the report.

4 Adverse-event-type codes

Table 1 specifies adverse-event-type codes.

Table 1 — Adverse-event-type codes

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
1000	Activation, Positioning or Separation	Issue associated with any deviations from device-documented performance specifications relating to the sequence of events for activation or positioning of the device or one of its components into a specific body location. NOTE 1 “Deployment” is synonymous with “activation”.	1001	Difficult to Position	Issue associated with users experiencing difficulty or uneasiness to deploy a device, device component, or both, to a specified location.
			1002	Failure to Activate	Issue associated with the inability of a device or device component to be activated.
			1003	Failure to Separate	Issue associated with the failure of the device or one of its components to detach or separate as intended.
			1004	Premature Activation	Issue associated with an early and unexpected activation of the device, device component, or both, from the system.
			1005	Delayed Activation	Issue associated with a delayed and unexpected activation of the device, device component, or both, from the system.