TECHNICAL SPECIFICATION

ISO/TS 19218-1

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Medical devices — Hierarchical coding structure for adverse events —

Part 1: Event-type codes

Dispositifs médicaux — Structure de codage pour la cause et le type d'événement défavorable —

Partie 1: Codes de type d'événement

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Foreword

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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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
1100	Computer Hardware	Issue associated with hardware that affects device performance or communication with another device.	1101	Hardware Issue	Issue associated with hardware that affects device performance.
			1102	Network Issue	Issue associated with the deviations from documented system specifications that affect overall system performance or the performance of an individual device or collection of devices connected to that system.
1200	Computer Software	Issue associated with written programs, codes or software system that affects device performance or communication with another device.	1201	Application Program Issue	Issue associated with the requirement for software to fulfil its function within an intended use or application.
			1202	Programming Issue	Issue associated with the written program code or application software used to satisfy a stated need or objective for functioning of the device, including incorrect software programming, dose, parameter and power calculations.
1300	Connection or Fitting	Issue associated with linking of device, device components, or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.	1301	Connection Issue	Issue associated with linking of a device, device component, or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.
			1302	Disconnection	Issue associated with a linked device, device component, or both, having a sufficient open space (disconnection) to prevent gas, liquid or electrical current flowing between connectors.
			1303	Failure to Disconnect	Issue associated with the linking of a device, device component, or both, whereby termination of the transfer of liquid, gas, electricity or information cannot be accomplished, or linking components do not come apart, or disconnect, when expected.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
			1304	Fitting Problem	Issue associated with the connection of a device, device component, or both, whereby channels, switching systems and other functional units set up to provide means for a transfer of liquid, gas, electricity or information do not match or fit.
			1305	Loose or Intermittent Connection	Issue associated with the connection of a device or device component being loose or intermittent.
			1306	Misconnection	Issue associated with the improper connection of a device, device component or a connection not in accordance with device specifications.
1400	Electrical/ Electronic	Issue associated with a failure of the electrical or electronic circuitry or components of the device.	1401	Arcing	Issue associated with electrical current flowing through a gap between two conductive surfaces, typically resulting in a visible flash of light.
			1402	Circuit Failure	Issue associated with a failure of the internal network paths or electrical circuitry (i.e. electrical components, circuit boards, wiring).
			1403	Device Sensing Issue	Issue associated with device features that are designed to respond to a physical stimulus (temperature, illumination, motion, cardiac rhythms) that do not transmit a resulting signal for interpretation or measurement.
			1404	Power Source Issue	Issue associated with the internal power of the device (e.g. battery, transformer, fuel cell or other power sources).
			1405	Spark	Issue associated with the discharge of electricity between two bodies previously electrically charged (e.g. electrostatic discharge).

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
1500	External Conditions	Issue associated with the surrounding conditions in which the device is being used or stored, such as temperature, noise, lighting, ventilation or power supply.	1501	Environmental Particulates	Issue associated with fine solids or liquid particles, such as dust, smoke, fumes or mist suspended in the immediate atmosphere in which the device is being used.
			1502	Fumes or Vapours	Issue associated with the visibility, odour or toxicity of an ambient vapour or gas which affects the operation of the device.
			1503	Inadequate Storage	Issue associated with inadequate or inappropriate storage of the device.
			1504	Loss of Power	Issue associated with the failure of primary power provided by the facility (e.g. electrical, gas, fluid pressure).
1600	Implantable Device Failure	The migration, malfunction or failure of an implanted device (active or non-active).	1601	Migration of Device or Device Component	Issue associated with an undesired movement of a device, device component, or both, related to its movement away from or dislodging from a source.
			1602	Osseo-disintegration Issue	Issue associated with interconnection between bone and an implanted device.
1700	Incompatibility	Issue associated with the device not being compatible with another device component, patient or substance (medication, body fluid, etc.) that it contains or transports.	1701	Component or Accessory Incompatibility	Issue associated with the incompatibility of any device, device component, or both, while being operated in the same use environment, thereby leading to a dysfunction between the device and its components.
			1702	Device-Device Incompatibility	Issue associated with the incompatibility of two or more devices while being operated in the same use environment, thereby leading to a dysfunction of more than one device.
			1703	Patient-Device Incompatibility	Issue associated with the interaction between the patient's physiology or anatomy and the device that affects the patient or device (e.g. biocompatibility or immunological issues).

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
1800	Infusion/Flow	Issue associated with the device failing to deliver liquids or gases as intended (e.g. delivering drugs at incorrect rate, issues with drawing fluid from a system, etc.).	1801	Deflation Issue	Issue associated with the inability of a device, device component, or both, to release its contents.
			1802	Improper Flow or Infusion	Issue associated with the unsubstantiated regulation and delivery of therapy (e.g. air, gas, drugs or fluids into a device or a patient under positive pressure that is being generated by a pump).
			1803	Inflation Issue	Issue associated with the inability of a device, device component, or both, to expand or enlarge with the intended inflation agent (e.g. saline or air).
			1804	No Flow	Issue arising from the device failing to deliver the specified liquid or gas.
			1805	Excessive Flow or Overinfusion	Issue associated with an overdose of delivery therapy, such as drugs or fluids being delivered into a device or a patient under positive pressure.
			1806	Insufficient Flow or Underinfusion	Issue associated with an underdose of therapy (e.g. epidural, intrathecal, intravenous, subcutaneous, such as drugs or fluids being delivered into a device or a patient under positive pressure).
1900	Marking, Labelling or Instructions for Use	Issue associated with the accuracy and appropriateness of any written, printed, graphic or audio/visual matter that is supplied with a medical device or its package. NOTE 2 Includes markings that appear directly on the device.	1901	Instructions for Use Issue	Issue associated with any matter that accompanies a medical device, including instructions related to identification, technical description and use of the medical device provided by the device manufacturer.
			1902	Markings Issue	Issue associated with the written, printed or graphic material that is affixed to a medical device or any of its packaging or accompanying materials.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
2000	Material	Issue associated with any deviations from device-documented performance specifications relating to the limited durability of all material used to construct the device.	2001	Burst	Issue associated with the pressure inside a vessel or container rising to such a degree that the container or vessel ruptures.
			2002	Crack	Issue associated with an undesired separation or a visible opening along the length or width in the materials that are used in device construction.
			2003	Degrade	Issue associated with a deleterious change in the chemical structure, physical properties or appearance in the materials that are used in device construction.
			2004	Material Discoloured	Issue associated with an undesired streak, pattern or a noticeable change in colour.
			2005	Material Fragmentation	Issue associated with small pieces of the device breaking off unexpectedly.
			2006	Material Perforation	Issue associated with an undesired material damage characterized by closely spaced punched or drilled hole(s).
			2007	Material Separation	Issue associated with an undesired disassociation or breaking apart of device materials.
2100	Mechanical	Issue associated with any deviations from device-documented performance specifications relating to mechanical defects, including moving parts or subassemblies, etc.	2101	Calibration	Issue associated with the operation of the device, related to its accuracy and associated with the calibration of the device.
			2102	Detachment of Device or Device Component	Issue associated with the separation of devices or device components.
			2103	Dislodged or Dislocated	Issue associated with mechanical forces that displace devices or device components from an intended location.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
			2104	Leak	Issue associated with the escape of a liquid or gas from the vessel or container in which it is housed.
			2105	Mechanical Jam	Issue associated with a problem that prevents or restricts the movement of the device or its components.
			2106	Retraction Problem	Issue associated with drawing back the device, device component, or both, to an intended location.
			2107	Unintended Movement	Issue associated with an undesired movement of a device, which may be related to device malfunction, misdiagnosis or mistreatment.
2200	Non-Mechanical	Issues associated with any deviations from device-documented performance specifications relating to chemical, communications, optical or installation.	2201	Chemical Issue	Issue associated with any deviations from device-documented performance specifications relating to any chemical characterization (i.e. element, compound or mixture).
			2202	Communication or Transmission Level	Issue associated with the device sending or receiving signals or data. This includes transmission among internal components of the device and other external devices to which the device is intended to communicate.
			2203	Installation-Related	Issue associated with unsatisfactory installation, configuration or set-up of a specific device or technology.
			2204	Optical Issue	Issue associated with problems transmitting visible light, affecting the quality of the image transmitted or otherwise affecting the intended application of the visible light path.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
			2205	Telemetry Discrepancy	Issue associated with variability of the transmission of signals, which can be characterized as telemetry channel coding, a method of processing data sent from a source to a destination so that distinct messages are created which are easily distinguishable from one another.
2300	Other	An event type not otherwise included in this table resulting in a device-related event.	2301	Other	An event type not otherwise included in this table resulting in a device-related event.
2400	Output Issue	Issue associated with any deviation from a device's intended performance relating to the end result (e.g. data or test results).	2401	Energy Output to Patient Tissue Incorrect	Issue associated with the amount of energy directed to patient tissue.
			2402	Incorrect or Inadequate Result	Issue associated with end results provided by the device that do not conform to its performance specifications.
			2403	No Device Output	Issue associated with no measurement outcome, value or data obtained from the device.
2500	Packaging/ Shipping	Issue associated with packaging or shipping.	2501	Damage Prior to Use	Issue associated with packaging or shipping damage prior to the use of the device.
			2502	Delivered as Unsterile Product	Issue associated with the device delivered unsterile due to loss of packaging integrity.
			2503	Packaging	Issue associated with the materials used for protective shipping or shipping instructions.
			2504	Item Contaminated during Shipping	Issue associated with the presence of any unexpected foreign substance found on the surface or in the package materials, which may affect performance for its intended use.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
			2505	Difficult to Open or Remove Packaging Material	Issue associated with difficulty for end-users to operate the device, specifically as it relates to the opening or removal of the outer wrapping.
2600	Protective	Issue associated with any deviations from device-documented performance specifications relating to the implemented and inherited design features specific to devices used for reducing risks to patient or care-giver or maintaining risks within specified levels.	2601	Device Alarm System Issue	Issue associated with the failure of an alarm system.
			2602	Fail-Safe Issue	Issue associated with a device feature that prevents the unsafe use of the device.
2700	Temperature	Issue associated with the device producing unintended temperatures.	2701	Burned Device or Component	Issue associated with a discoloration or destruction as a result of thermal decomposition of the device or its components.
			2702	Fire	Issue associated with the combustion of device components, resulting in any of the following: light, flame, smoke.
			2703	Flare or Flash	Issue associated with a device-related burn with an unsteady flame.
			2704	Insufficient Cooling	Issue associated with the device or device parts being insufficiently cool in either device active (working) or non-active (non-working) state.
			2705	Overheat of Device or Device Component	Issue associated with the device producing high temperatures, such that its operation is compromised (e.g. overheating that produces melting of components or automatic shutdown).
			2706	Smoking	Issue associated with a cloud of vapour or gas generated from the device, generally associated after a fire or a burn.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
2800	Unintended Function	Issue associated with the device not working as intended, resulting in malfunction, misdiagnosis or mistreatment.	2801	Device Displays Incorrect Message	Issue associated with a device prompting the user with incorrect information in order to indicate a device problem.
			2802	Failure to Adhere or Bond	Issue associated with difficulties in attaching a device to another object including another device or device component, or to a patient body part.
			2803	Misassembled	Issue associated with the use of the device characterized by incorrect assembly of device components, parts or constituents.
			2804	Therapy Delivered to Incorrect Body Area	Issue associated with energy delivered to an incorrect body area.
2900	Use Error	Issue associated with an act or omission of an act that has a different result than that intended by the manufacturer or expected by the operator.	2901	Inadequate or Inappropriate Disinfection or Sterilization	Issue associated with the undesired introduction of impurities to a device, or the insufficient removal of any visible soil, foreign material or organism deposits on the external surfaces, crevices and joints of a device by a mechanical or manual process intended to render the device sterile, safe for handling, or for further processes to decontaminate.
			2902	Inadequate Training	Issue associated with facility not providing satisfactory initial or periodic user training, covering operation of the device.
			2903	Maintenance Issue	Issue associated with the servicing of a device.
			2904	Refurbishing Issue	Issue associated with the refurbishing of a device.
			2905	Use of Device Issue	Issue associated with the user's failure to process, service or operate the device according to the manufacturer's recommendations or recognized best practices.
			2906	Device Inoperable	Issue associated with the device being in a non-functional or inoperable state.

Annex A
(informative)

Coding-system structure

The complete coding system has a structure of five data points for useful and accurate reporting on medical device adverse events, in order to facilitate global data exchange between regulatory bodies. Certain information is needed in order to identify correctly the device and a selection of one or more event types and evaluation codes to define the incident. The five data points are as shown in Figure A.1.

Device nomenclature code	Device type	Adverse-event-type code	Adverse-event evaluation code	Patient/user/other person outcome code (optional)

Figure A.1 — Coding system structure

— The **device nomenclature code** refers to a unique code determined by the device category, generic device group and device type, i.e. GMDN (Global Medical Device Nomenclature) or other device nomenclatures such as UMDNS (Universal Medical Device Nomenclature System).

— The **device type** refers to identification of a manufacturer's specific product (i.e. make and model) as defined in ISO 15225[1].

— The **adverse-event-type code** refers to the codes in Table 1. These codes have been included based on the most commonly used event data from various sources.

— The **adverse-event evaluation code** refers to codes that describe the results of the evaluation of the event.

NOTE The adverse-event evaluation code is not included in this part of ISO/TS 19218. These codes are under development in ISO/TS 19218-2.

— The **patient/user/other person outcome code** refers to codes developed and maintained in databases such as SNOMED (Systematized Nomenclature of Medicine) and MEDDRA (Medical Dictionary for Regulatory Activities). The codes can identify an outcome as a result of an adverse event.

Using a complete system does more than just provide a code for an adverse event. Using a complete system can help make an association between an adverse event and an adverse consequence to a patient.

Annex B
(informative)

Examples of event-type code selection

This annex provides examples of event-type code selection. The examples do not address reportability and are not suggested as being reportable to a regulatory authority.

Both levels of the code could be used: the instructions for the selection of codes could state that, if an appropriate Level 2 code cannot be found, then a Level 1 code should be used.

EXAMPLE 1 A medical facility reports to the manufacturer that an infusion pump started to smoke and then caught on fire.

— Codes 2702 (Fire) and 2706 (Smoking) would be selected if coding at Level 2.

— Code 2700 (Temperature) would be selected if coding at Level 1.

— Environmental codes would not be used because the source of the heat and smoke was the device itself and the external environment did not contribute to the event.

EXAMPLE 2 A medical facility determines that it is not able to connect two components of an anaesthesiology circuit. Although the labels for the two components indicate that they are of the correct size, one of the components is determined to be labelled with the wrong size.

— Codes 1304 (Fitting Problem) and 1902 (Markings Issue) would be selected if coding at Level 2.

— Codes 1300 (Connection or Fitting) and 1900 (Marking, Labelling or Instructions for Use) would be selected if coding at Level 1.

— If the medical facility had not determined that there was a size issue, Code 1301 (Connection Issue) would have been selected.

— Due to the size error appearing on the label, Code 1901 (Instructions for Use Issue) would not have been selected.

— Since there is a connection issue, Code 1702 (Device-Device Incompatibility) would not be a suitable code.

— If there was not a specific code addressing the device-device issue [i.e. Code 1301 (Connection Issue)], then Code 1703 (Patient-Device Incompatibility) would have been appropriate.

EXAMPLE 3 A device is being used at the patient's bedside to produce critical diagnostic data. It is determined that the data is not being received at the monitor in the nurse's station. Testing of the equipment leads to the conclusion that a piece of communications equipment in the computer network is the cause of the data not being transmitted.

— Code 2202 (Communication or Transmission Level) would be selected if coding at Level 2.

— Code 2200 (Non-Mechanical) would be selected if coding at Level 1.

— Code 1301 (Connection Issue) would not be selected because the lack of data transmission is due to the network connection between the two devices.

— Code 2403 (No Device Output) would not be selected because the device is producing diagnostic data, but it is not being transmitted.

— Code 1201 (Application Program Issue) would not be selected unless the failure of the data transmission was determined to be due to the application software obstructing the transmission of the data.

EXAMPLE 4 It was determined that a device failure led to the reduction in flow of a drug to the patient. The failure was due to the inflatable cuff of the pressure infuser for the intravenous bag not inflating. It was determined that a hole had developed in the cuff.

— Code 1803 (Inflation Issue) would be selected if coding at Level 2.

— Code 1800 (Infusion/Flow) would be selected if coding at Level 1.

— Code 1806 (Insufficient Flow or Underinfusion) would not be selected since the pump that was providing air to the cuff was operating properly.

EXAMPLE 5 A patient lift used to transfer a patient from a bed to a transport device fails and the patient falls to the floor. It is determined that the patient weighed more than the device was labelled to be able to handle.

— Codes 2107 (Unintended Movement) and 2905 (Use of Device Issue) would be selected if coding at Level 2.

— Codes 2100 (Mechanical) and 2900 (Use Error) would be selected if coding at Level 1.

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1) Under preparation.

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