TECHNICAL SPECIFICATION

ISO/TS 19218-2

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Medical devices — Hierarchical coding structure for adverse events —

Part 2: Evaluation codes

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

Partie 2: Codes d'évaluation

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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 document:

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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 19218-2 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

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

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

— *Part 1: Event-type codes*

— *Part 2: Evaluation codes*

Introduction

It is envisaged that the adverse-event evaluation codes specified in this part of ISO 19218 will originate primarily from the manufacturer of the device concerned. This Technical Specification provides a structure by which adverse-event evaluations can be used to collect medical device surveillance information in the post-market phase. It will also enable this information to be easily exchanged on an international basis using the common codes.

It can be used by healthcare providers and other users of the devices; however, a number of the evaluation codes characterize the results of analyses or investigations conducted by the manufacturer or regulatory authorities, who can use it to

— recognize the results of analyses or investigations of adverse events by means of globally recognized evaluation codes, and

— apply these codes as part of a medical device surveillance or reporting system.

Annex A shows how adverse-event codes can be used in conjunction with other data elements in order to facilitate global data exchange between regulatory bodies.

Medical devices — Hierarchical coding structure for adverse events —

Part 2: Evaluation codes

1 Scope

This part of ISO 19218 specifies requirements for a hierarchical coding structure for characterizing the results of the analysis or evaluation of adverse events relating to medical devices. The codes are intended primarily for use by medical device manufacturers and regulatory authorities. They can also be used for coding the results of the analysis or evaluation of events other than those related to death or serious injury, as well as malfunctions that could lead to death or serious injury.

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

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 has led to the death or serious injury of a patient, user or other person, or that might lead to the death or serious injury of a patient, user or other person if it were to reoccur

NOTE 1 This definition is consistent with guidance in GHTF/SG2/N54/R8:2006[5].

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

NOTE 3 This definition is not intended to be used in determining if an event is reportable to a regulatory authority.

2.2
serious injury
serious deterioration in 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 “Permanent” here means irreversible impairment or damage, excluding minor impairment or damage.

NOTE 2 This definition is consistent with guidance in GHTF/SG2/N54/R8:2006[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[6].

3 Adverse-event evaluation code requirements

The adverse-event evaluation code characterizes the latest conclusions of an analysis or investigation of the adverse event. The code shall be a five-digit numerical code selected from Table 1.

NOTE 1 Multiple codes can be necessary to fully describe the results of the evaluation of an adverse event.

NOTE 2 The adverse-event evaluation code can be useful for manufacturers and regulatory authorities when following up on reported adverse events. When combined with the adverse-event-type code, the characteristics of the adverse event are succinctly communicated.

NOTE 3 The latest conclusions characterize the event at any stage of an analysis or investigation.

4 Adverse-event evaluation codes

Table 1 specifies adverse-event evaluation codes.

Table 1 — Adverse-event evaluation codes

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
25000	Biological	Event relating to, caused by or affecting life or living organisms	25001	Abnormal or unexpected physiological response	Abnormal or unexpected physiological response such as hypersensitivity
			25002	Biocompatibility	Device causes cellular or tissue responses that elicit an undesirable local or systemic effect in the recipient or beneficiary of that therapy [see ISO 10993 (all parts)]
			25003	Biological material	Presence of biological material(s) in a device resulting in a reaction other than immediate hypersensitivity
			25004	Contamination by foreign material	Presence of extraneous material that renders a device impure or potentially harmful NOTE Excludes contamination during production (see level 2 code 26503).
			25005	Genotoxic problem	Device's ability to cause damage to genetic material, e.g. leading malignant tumours [see ISO 10993 (all parts)]
			25006	Hematologic problem	Device affects or impacts the blood or its components [see ISO 10993 (all parts)]
			25007	Endotoxin contamination	Undesirable presence of toxins associated with certain bacteria (e.g. gram negative bacteria)

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			25008	Microbiological contamination	Undesirable presence of microorganisms or microbes such as bacteria and fungi (yeasts and moulds)
			25009	Material or material leachate pyrogenic problem	Undesirable presence of pyrogens or fever-producing organisms resulting from materials that permeate through the device
25100	Counterfeiting	Event associated with the reproduction of a genuine medical device or the forging of labelling or product information with the intent to deceptively misrepresent the genuine medical product	25101	Counterfeit	Imitation of a genuine medical device with the intent to deceive
			25102	Forged product information	Product labelling or other information that is not provided or authorized by the company responsible for labelling the device
25300	Design	Event associated with the failure of a medical device to achieve its intended function due to inadequate design or development process	25301	Design deficiency	Failure of the device to achieve its intended function due to inadequate design, including inappropriate risk assessment
			25302	Development process deficiency	Failure of the device to achieve its intended function due to an inadequate development process
			25303	Packaging	Inadequate or inappropriate packaging
			25304	Safety measures	Inadequate or missing safety measures
			25305	Usability	Deficient or inadequate characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction NOTE Consistent with IEC 62366:2007, 3.17.
25500	Electrical	Event associated with an electrically powered device where an electrical malfunction results in a device failure (e.g. electrical circuitry, contact or component failed), even if the failure is intermittent	25501	Electrical component	Electrical or electronic component defect (e.g. resistor failure, capacitor failure, transformer failure, microprocessor failure) resulting in a device failure NOTE Excludes insulation breakdown (see level 2 code 25506).

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			25502	Electrical circuitry	Malfunction of an electrical circuit resulting from events such as fluid penetration or overheating
			25503	Electrical contact	Electrical issue resulting in the malfunction of the device (e.g. make or break a contact, corrosion, high-resistance, thermal shock, or unintentional movement)
			25504	Energy storage system	Device problem related to the electrical energy storage system (e.g. rechargeable battery, charging system or capacitor) and including problems such as premature power source depletion and battery explosions
			25505	Improper construction	Device problem related to improper wire routing, breakage due to unexpected movement and other construction deficiencies
			25506	Insulation	Device that has inadequate or incorrect insulation material, resulting in exposure to hazardous voltage
			25507	Power source — loss of power	Failure of the mains power, causing a device to cease to operate
25600	Electromagnetic interference	Event associated with the malfunction of an active, electrically powered medical device, caused by electromagnetic disturbance, including radio-frequency interference (RFI)	25601	Electromagnetic immunity	Medical device performance degradation resulting from an electromagnetic disturbance
			25602	Electromagnetic emissions	Medical devices that unintentionally emit electromagnetic disturbances that affect radio services, other equipment or the performance of other medical devices or medical systems

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
26000	Human factors	Event associated with the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations NOTE Consistent with AAMI HE75.	26001	Abnormal use	Act or omission of an act by the user or operator of the medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer, e.g. deliberate violation of instructions, procedures or use prior to completing installation, causing a device failure NOTE Consistent with IEC 62366:2007, 3.1.
			26002	Expiration date	Use of the medical device beyond the expiration date, resulting in a device failure
			26003	End of life	Device failure resulting from use beyond the intended useful life of the product
			26004	Inappropriate environment	Use of a device in an environment that results in a failure or malfunction
			26005	Incorrect calibration	Calibration performed incorrectly or not performed at all, resulting in inaccurate results provided by medical devices involved in measurements (e.g. temperature, weight, pH, IVD test results)
			26006	Installation problem	Device that malfunctions because incorrectly installed, set-up or configured
			26007	Maintenance	Failure or malfunction of a device resulting from inadequate routine or periodic maintenance
			26008	Non-hygienic condition	Device failure resulting from inadequate hygienic status of the user or locality of the user
			26009	Patient anatomy/ physiology	Device failure resulting from use inadequate or inappropriate for the anatomy/physiology of the patient involved
			26010	Patient condition	Failure or poor performance of a device resulting from the patient condition (possibly unexpected)
			26011	Sterilization, disinfection, cleaning	Failure of a device due to inadequate or inappropriate sterilization, disinfection, or cleaning

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			26012	Storage conditions	Device failure resulting from inappropriate or inadequate storage conditions (e.g. temperature, humidity, light exposure)
			26013	Training	Device failure resulting from the lack of or inadequate training of the user
			26014	Use error	Act or omission of an act that has a different result than that intended by the manufacturer or expected by the operator causing a device failure NOTE Consistent with IEC 62366:2007, definition 3.21.
26200	Interoperability	An event associated with heterogeneous medical devices and other equipment integrated to create a medical system	26201	Communications (wired or wireless)	Medical devices that do not send or receive adequate signals such as messages received but not understood, messages sent but not received, or message content corrupted
			26202	Disconnection	Unintended separation of a connection between two or more parts of the medical system, (e.g. electrical, mechanical, tubing), causing device failure
			26203	Incompatibility between device systems or components	Device that malfunctions due to a connection or attachment of inappropriate components
26400	Labelling	Event associated with the information supplied by the manufacturer for the safe, easy and efficient operation of a medical device	26401	Error in the label or instructions for use	Device failure resulting from inaccurate labelling
			26402	Insufficient instructions for use	Device error resulting from inadequate or missing information in the labelling
			26403	Labelling unreadable	Device error resulting from the user's inability to read the labelling, e.g. damaged label, degradation, font size
26500	Manufacturing	Event associated with a medical device that can be traced back to a problem in the manufacturing process, excluding medical device design issues	26501	Assembly problem	Device failure resulting from incorrect assembly
			26502	Cleaning or disinfecting process	Device failure resulting from inadequate cleaning or disinfection

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			26503	Contamination during production	Device is affected/impeded by exposure to corrupting elements or pollution from production that was not removed adequately by further processing
			26504	Sterilization process	Device failure resulting from inappropriate or inadequate sterilization
			26505	Manufacturing equipment problem	Device failure due to a problem in the equipment used in the manufacturing process or in the maintenance of that equipment
			26506	Packaging problem	Device failure resulting from degradation of the packaging [e.g. broken seal or ripping (compromised), IVD kit container]
			26507	Quality control problem	Device problem resulting from the failure to maintain or establish techniques for controlling and verifying the product specifications identified by the manufacturer
			26508	Storage problem	Device failure resulting from inappropriate or inadequate storage conditions (e.g. temperature, humidity, light exposure)
26600	Materials, chemistry	Event associated with device components or materials, or how device materials or components react to other elements, either within the medical device or in its environment	26601	Degradation problem	Device problem that results from a device becoming worn, weakened, corroded or broken down due to processes such as aging, permeation and corrosion
			26602	Improper material	Device problem resulting from the use of an inappropriate material for the intended use of the product
			26603	Incompatible material	Device failure resulting from the use of incompatible materials during the life-time of the product, e.g. wear, corrosion
			26604	Reactivity problem	Device problem related to materials that do not react as intended, e.g. amalgam, impression materials, silicone

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			26605	Damage due to sterilant/ cleaning process	Device failure resulting in material damage as the result of a chemical agent used during the sterilization or cleaning process, e.g. excessive residual chemical or incompatible sterilant
26700	Mechanical	Event associated with the machinery or physical properties of the medical device excluding electrical properties	26701	Component malfunction	Mechanical component defect resulting in a device failure, such as failure of a support bracket
			26702	Fatigue	Device problem due to the weakening or breakdown of the material when subjected to stress or a series of repeated stresses
			26703	Fracture	Device problem resulting from the separation of a component, object or material into two or more pieces
			26704	Leakage/seal	Device failure due to a substance, usually liquid or gas, leaked from the device or failure of a seal allowing a substance to enter or exit a device or component
			26705	Wear	Device problem due to the premature or expected erosion of its material by use, deterioration or change
26800	No medical device problem or failure detected	Event associated with a medical device where it either functioned as designed or a failure was not found	26801	No medical device problem	Determination made that the device functioned as intended
			26802	No medical device failure detected	Failure of the device could not be confirmed due to insufficient evidence
26900	Not medical-device related	Event that is not associated or related to the medical device	26901	Not medical device related	Adverse event is not related to the device
27000	Off-label, unapproved, or contraindicated use	Event associated with the non-intended (off-label) use, use without regulatory approval (unapproved), or contraindicated use of a medical device	27001	Off-label use	Use of a medical device beyond that intended by the manufacturer and for which no regulatory clearance has been obtained
			27002	Unapproved use	Use of a device for a medical purpose that does not have regulatory approval or has new intended uses that have not yet received additional clearance

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			27003	Contraindicated use	Problem due to the device being used for a purpose that was contraindicated by the manufacturer
27100	Operational Problem (functional deficiency)	Event associated with the lack or impairment of a functional capacity or capability of a medical device	27101	Alarm	Alarm failed or was inadequate
			27102	Erroneous data transfer	Failure of a medical device to accurately transfer data to or from another device or location
			27103	Failure to calibrate	Failure of a device requiring calibration through failure to be calibrated, resulting in inaccurate readings
			27104	Protective measure	Failure of a protective measure, e.g. needle guard, pressure relief valve NOTE Excludes alarms (see level 2 code 27101).
			27105	Thermal issue	Failure of a device due to excessive heating or cooling
			27106	Usability	Device failure due to inadequate usability NOTE Consistent with IEC 62366:2007, 3.17.
27200	Optical	Event associated with the medical device's ability to pass light energy	27201	Optical transmission problem	Problem with the device's ability to pass light energy
27300	Other	Device-related event associated with an evaluation term not otherwise included in this code	27301	Other	Device-related event not otherwise included in this table
27500	Product distribution	Event associated with a medical device that can be traced back to a problem in distribution prior to first use. NOTE Excludes the level 2 terms in level 1 codes 25300 and 26500.	27501	Contamination prior to first use	Device is affected/impeded by exposure to corrupting elements, pollution or contaminants that can affect a component, part or the entire device
			27502	Quality assurance in healthcare facility	Device failure due to inadequate quality assurance procedures in the healthcare facility
			27503	Installation problem	Device failure due to an installation error by the manufacturer or a party in the distribution chain

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			27504	Transportation, handling, delivery	Device problem due to how the device was shipped e.g. temperature of the shipping compartment, method of transportation
27700	Quality system	Event associated with medical device problems resulting from the failure to maintain or establish techniques for controlling and verifying the product specifications identified by the manufacturer	27701	Quality control problem	Device problem that results from the failure to maintain or establish techniques for controlling and verifying the product specifications identified by the manufacturer
28000	Reuse of a single-use device	Event associated with the reuse of a medical device intended by its manufacturer to be for single-use only	28001	Reuse of a single use device	Device failure due to the reuse of a disposable device intended to be used only once
28200	Software	Event associated with the medical device function or device-generated information that is impaired, incorrect or unreliable due to a software malfunction, inadequacy or incompatibility NOTE These conditions include defective or inadequate programming, obsolete software and wrong installation, including upgrades.	28201	Software configuration	Device problem due to use of an incorrect version or inadequate change control
			28202	Software design error	Medical device or component failure due to incomplete, incorrect, or inadequate software design
			28203	Software installation problem	Medical device failure due to software installation not performed as specified
			28204	Software requirement error	Medical device failure due to a software requirement error, e.g. requirements for the device are either incomplete, inadequate or in conflict
			28205	Software security vulnerability	Medical device software failure due to inadequate authorization, access control and accountability features
			28206	Hardware incompatibility	Device failure due to the connection of two or more incompatible devices
			28207	Software incompatibility	Device failure due to the connection of two or more incompatible pieces of software

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
28500	Tampering, sabotage	Event associated with an intentional act to interfere with the manufacturing and distribution of the device as intended by the manufacturer (sabotage), or the manipulation of the manufacturer's device while in medical use (tampering) resulting in a medical device malfunction and/or an adverse effect on patient care NOTE This can include interference of the device settings or function by the patient or a third party, with intent to alter the patient treatment situation, or undermining the reputation of a device type (make and model) and/or its manufacturer by interfering with the manufacturing process, resulting in an unreliable product.	28501	Tampering, sabotage	Device failure resulting from the tampering or sabotage of a genuine medical device
28700	Test results	Event associated with the generation and supply of inaccurate test results	28701	False or inaccurate test result	Device not complying with its specific performance characteristics, resulting in a false test result (e.g. a false-positive or false-negative) or inaccurate test result NOTE Performance characteristics can include diagnostic sensitivity, diagnostic specificity, linearity, stability, interference.
29000	Unidentified	Event for which no probable or definitive cause can be determined	29001	Unidentified	No probable or definitive cause determined — unknown condition causing failure of the device operating function

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, intended 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 shown in Figure A.1 and explained below.

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 the identification of a manufacturer's specific product (i.e. make and model), as defined in ISO 15225.

— The *adverse-event-type code* refers to the code that characterizes the observed use/malfunction/failure of the medical device at the time the event occurred.

— The *adverse-event evaluation code* refers to codes in Table 1 that describe the results of the evaluation of the event.

NOTE The adverse-event-type code is not included in this part of ISO 19218. These codes are given in ISO/TS 19218-1.

— 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; it can help make an association between an adverse event and an adverse consequence to a patient.

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