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AMENDMENT 1
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Medical devices — Hierarchical coding structure for adverse events —

Part 1: Event-type codes

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

Partie 1: Codes de type d'événement

AMENDEMENT 1

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Amendment 1 to ISO/TS 19218-1:2011 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

Medical devices — Hierarchical coding structure for adverse events —

Part 1: Event-type codes

AMENDMENT 1

Page 2, Clause 4

In Table 1, replace the fourth, fifth and sixth columns with the following:

Level 2 code	Level 2 term	Level 2 definition	Example(s)
1001	Difficult to Position	Issue associated with users experiencing difficulty in deploying a device, device component or both to a specified location.	When replacing a left ventricle lead, the physician had difficulty moving the lead around a bend in a branch of the coronary sinus and so had to remove the lead and use another one.
1002	Failure to Activate	Issue associated with the inability of a device or device component to be activated.	The remote monitor of a patient monitoring system was not receiving any power because the power cord was faulty. A defibrillator failed to deliver a shock to a patient because the electrical connection between the device cable and the electrode paddle failed.
1003	Failure to Separate	Issue associated with the failure of the device or one of its components to detach or separate as intended.	Failure of a unidirectional valve in an anaesthesia machine allowed CO_2 rebreathing in the inspiratory limb of the breathing circuit.
1004	Premature Activation	Issue associated with an early and unexpected activation of the device, device component, or both, from the system.	When an intra-oral X-ray unit was first turned on, it generated an exposure on its own.
1005	Delayed Activation	Issue associated with a delayed and unexpected activation of the device, device component, or both from the system.	After a delay of several seconds, the defibrillator delivered a shock.
1101	Hardware Issue	Issue associated with hardware that affects device performance.	A fluoroscopic X-ray system stopped operating due to the failure of the hard drive.
1102	Network Issue	Issue associated with deviations from documented network system specifications that affect performance of the whole system or device or devices connected to the network.	Radiation treatment planning (RTP) data was transmitted across a general use hospital information network. There was a delay in the transfer of the data due to the RTP application running into conflict with other application demands on the network resources.
1201	Application Program Issue	Issue associated with the requirement for software to fulfil its function within an intended use or application.	During the use of a patient database application, the computer locked up and the data could not be saved.
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.	A nurse programmed an infusion pump with a dose that was outside the permissible limits for that drug, which the software did not identify, resulting in the patient receiving an overdose of the drug.

Level 2 code	Level 2 term	Level 2 definition	Example(s)
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.	Syringe pump did not recognize its dedicated syringe.
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.	Two components of a breathing circuit became disconnected.
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.	During a reintervention to address dislodgement of a pacemaker lead, the physician was not able to loosen the set-screw connecting the lead to the pacemaker. This resulted in both the lead and pacemaker having to be replaced.
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.	Syringe pump did not accommodate its dedicated syringe. An infusion pump designed for use with standard-sized tubing did not accommodate tubing from another manufacturer.
1305	Loose or Intermittent Connection	Issue associated with the connection of a device or device component being loose or intermittent.	A fluoroscopic X-ray device did not produce an exposure due to a bad interconnection cable that caused an intermittent connection to the X-ray generator.
1306	Misconnection	Issue associated with the improper connection of a device, device component or a connection not in accordance with device specifications.	Patient's enteral feeding tube was connected to the peripheral intravenous administration set instead of to the gavage tube.
1401	Arcing	Issue associated with electrical current flowing through a gap between two conductive surfaces, typically resulting in a visible flash of light.	Arcing between a power cord and a device occurred at their point of contact.
1402	Circuit Failure	Issue associated with a failure of the internal network paths or electrical circuitry (i.e. electrical components, circuit boards, wiring).	The circuit board in a perfusion pump failed, causing it to not cool the heart surgery solution to the correct temperature.
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.	An analyser's waste sensor failed to generate a waste full message and, as a result, the waste container overflowed.
1404	Power Source Issue	Issue associated with the internal power of the device (e.g. battery, transformer, fuel cell or other power sources).	The battery for a powered wheelchair did not have enough stored energy to power the chair for the period of time specified in the labelling.
1405	Spark	Issue associated with the discharge of electricity between two bodies previously electrically charged (e.g. electrostatic discharge).	Due to an electrostatic discharge between an electrically-charged nurse wearing shoes without rubber soles and a patient ventilator, the display screen of the device went blank.
1501	Environmental Particulates	Issue associated with fine solids or liquid particles such as dust, smoke, fume or mist suspended in the immediate atmosphere in which the device is being used.	A device system pump component emitted an oil mist.

Level 2 code	Level 2 term	Level 2 definition	Example(s)
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.	Due to inadequate room ventilation, an abnormally high concentration of carbon dioxide in the room caused an IVD autoanalyser being used to measure blood carbon dioxide levels to generate erroneous test results.
1503	Inadequate Storage	Issue associated with inadequate or inappropriate storage of the device.	As a result of the user storing the test strips in a plastic bag instead of the original container, the glucose monitor reported erroneous readings that resulted in unnecessary treatment.
1504	Loss of Power	Issue associated with the failure of primary power provided by the facility, e.g. electrical, gas, fluid pressure.	A patient was being transported by helicopter. The intra-aortic balloon pump was plugged into a power inverter that failed, which resulted in loss of power to the balloon pump.
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.	After a stenting procedure was completed, it was determined that the stent migrated and no longer completely covered the lesion.
1602	Osseo-disintegration Issue	Issue association with interconnection between bone and an implanted device.	Due to loosening of the connection between the hip implant and the femur, the patient required revision to address persistent pain.
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.	When the bulb in a phototherapy lamp burned out, the neonatal intensive care unit nurse replaced it with a bulb that did not meet the manufacturer's specifications. The lamp overheated and burned the baby's skin.
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.	Users of a newly distributed enhanced algorithm found the algorithm was incompatible with the electrocardiograph's operating software, resulting in operational errors.
1703	Patient-Device Incompatibility	Issue associated with the interaction between the patient's physiology or anatomy and the device that affects patient or device (e.g. biocompatibility or immunological issues).	During a procedure to replace a right ventricular lead, the placement was not successful due to the size of the patient's vein.
1801	Deflation Issue	Issue associated with the inability of a device, device component, or both, to release its contents.	After the balloon of a percutaneous transluminal angioplasty (PTA) balloon dilatation catheter was inflated, it could not be deflated without surgical intervention.
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.	An infusion pump delivered a larger volume of drug than programmed to deliver. The total parenteral nutrition solution was improperly mixed and, when the bag was connected for infusion, the pump was unable to deliver the solution because it clogged the tubing.
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).	During a blood pressure reading, the limb cuff continued to inflate to a level beyond normal practice.
1804	No Flow	Issue arising from the device failing to deliver the specified liquid or gas.	A ventilator alarmed due to a valve stuck in a closed condition blocking flow of oxygen to the patient.
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.	The infusion pump operator inadvertently entered an inappropriately high value for the volume of drug to be infused.

Level 2 code	Level 2 term	Level 2 definition	Example(s)
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.	During a phacofragmentation procedure, the viscous gas fluid injection system indicated that there was a reduced flow from the system.
1901	Instruction 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.	During a procedure to implant a pacing lead, the physician was confused by a figure of the helix gap that appeared in the lead's instructions for use and contacted the manufacturer for clarification.
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.	The radiopaque marker bands on the balloon catheter, required for repair of an arterial lesion, were unable to be visualized under fluoroscopy. Re-positioning the balloon and changing imaging techniques were unsuccessful in allowing visualization of the radiopaque marker bands.
2001	Burst	Issue associated with the pressure inside a vessel or container rising to such a degree that the container or vessel ruptures.	In the process of using a radio frequency sealer to seal the passageways between the large and small compartments of a cord blood freezing bag, the bag burst.
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.	During the adjustment of a monitor the supporting arm cracked, causing the monitor to fall out of position.
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.	The insulation on the atrial and ventricular leads on a patient's implanted cardiovascular pacemaker had degraded to the point that the leads had to be replaced. A reusable artery clamp showed signs of pitting and corrosion after several uses.
2004	Material Discoloured	Issue associated with an undesired streak, pattern or a noticeable change in colour.	An implanted intraocular lens showed a brownish discolouration.
2005	Material Fragmentation	Issue associated with small pieces of the device breaking off unexpectedly.	During a surgical procedure, the tip of the stainless steel surgical scissors broke off and fell into the surgical site.
2006	Material Perforation	Issue associated with an undesired material damage characterized by closely spaced punched or drilled holes.	During preparation for an angioplasty procedure, the guide wire came out the side of the balloon catheter.
2007	Material Separation	Issue associated with an undesired disassociation or breaking apart of device materials.	A patient's incision reopened because the surgical mesh used in the closure procedure became delaminated.
2101	Calibration	Issue associated with the operation of the device, related to its accuracy, and associated with the calibration of the device.	The electronic gas delivery system would not calibrate during the preparation of the device for use in a cardiopulmonary bypass procedure and an error message was observed.
2102	Detachment of Device or Device Component	Issue associated with the detachment of devices or device components.	While advancing a urethral stent into the kidney, the silver tip of the stent pusher became disengaged from the shaft. When the clinician attempted to remove the patient's epidural catheter two hours after childbirth, a piece of the catheter broke off and had to be surgically removed.
2103	Dislodged or Dislocated	Issue associated with mechanical forces that displace devices or device components from an intended location.	During coronary bypass surgery, the pacemaker lead was dislodged.
2104	Leak	Issue associated with the escape of a liquid or gas from the vessel or container in which it is housed.	During the use of a hydrothermablation procedure set, the short tubing on the top part of the fluid collection bag leaked.

Level 2 code	Level 2 term	Level 2 definition	Example(s)
2105	Mechanical Jam	Issue associated with a problem that prevents or restricts the movement of the device or its components.	During a thoracic procedure, the stapler jammed after firing only one staple.
2106	Retraction Problem	Issue associated with drawing back the device, device component, or both, to an intended location.	The safety shield on a syringe failed to retract and resulted in the nurse receiving a needlestick injury.
2107	Unintended Movement	Issue associated with an undesired movement of a device, which may be related to device malfunction, misdiagnosis or mistreatment.	The X-ray tabletop locks disengaged, resulting in the tabletop free-floating in the longitudinal and lateral directions.
2201	Chemical Issue	Issue associated with any deviations from device documented performance specifications relating to any chemical characterization, i.e. element, compound or mixture.	Test strips for an IVD device were manufactured with contaminated reagents, causing the device to generate erroneous diagnostic readings.
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.	A telemetry device was not sending data to a central monitoring unit, which led to incorrect treatment of the patient.
2203	Installation-Related	Issue associated with unsatisfactory installation, configuration or setup of a specific device or technology.	A mammography machine was set up without beam filtration and resulted in extreme radiation overexposure to the patient.
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.	During a vein harvesting procedure the endoscopic device transmitted an inadequate amount of light making the displayed image very dark.
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.	The algorithm incorporated into a telemetry receiving unit was intended to correct signal errors without needing to interrogate the sending unit. Due to an error in the software logic, the receiving unit accepted incorrect data but did not apply the algorithm to correct the errors before it stored the data.
2301	Other	An event type not otherwise included in this table resulting in a device related event.	
2401	Energy Output to Patient Tissue Incorrect	Issue associated with the amount of energy directed to patient tissue.	During surgery a patient was burned due to an electrosurgical unit that delivered excessive energy.
2402	Incorrect or Inadequate Result	Issue associated with end results provided by the device that does not conform to its performance specifications.	A prothrombin meter used by a patient at home returned test results that were inaccurately low, causing the patient to self-medicate inappropriately.
2403	No Device Output	Issue associated with no measurement outcome, value, or data obtained from the device.	A prothrombin home test meter did not report an INR (international normalized ratio) value. Despite a patient's repeated attempts to use and recalibrate a glucose meter, the screen continually displayed an error message.
2501	Damage Prior to Use	Issue associated with packaging or shipping damage prior to the use of the device.	An intraocular lens was damaged while being removed from its packaging.
2502	Delivered as Unsterile Product	Issue associated with the device delivered unsterile due to loss of packaging integrity.	Due to a compromised seal that allowed ingress of microorganisms, the sterile device could not be used during surgery.

Level 2 code	Level 2 term	Level 2 definition	Example(s)
2503	Packaging	Issue associated with the materials used for protective shipping or shipping instructions.	The device was damaged due to packaging materials that were too weak to withstand rough handling during transportation.
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.	During shipment to the hospital, a solvent soaked into the device packaging.
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.	The aseptic presentation of a sterile device was compromised when a nurse had difficulty opening its packaging due to excessive seal strength. When the nurse pulled hard enough to overcome the seal, the packaging opened suddenly and the device fell to the floor.
2601	Device Alarm System Issue	Issue associated with the failure of an alarm system.	A ventilator did not alarm when an obstruction in the patient airway caused reduced airflow to the patient.
2602	Fail-Safe Issue	Issue associated with a device feature that prevents the unsafe use of the device.	Prior to a biopsy procedure, the reusable core biopsy driver was found to be firing while the safety was on.
2701	Burned Device or Component	Issues associated with a discolouration or destruction as a result of thermal decomposition of the device or its components.	Burn marks were observed on the inside face of the glucose monitor display.
2702	Fire	Issues associated with the combustion of device components, resulting in any of the following: light, flame, smoke.	A break in a cable caused an electrical spark during a surgical procedure that resulted in the patient wrapping catching on fire.
2703	Flare or Flash	Issue associated with device-related burn with an unsteady flame.	When a breast pump was plugged into an electrical outlet, a flash of flame was seen and the plug was irreparably damaged.
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.	A magnetic resonance imaging device failure was caused by the radio frequency (RF) coils reaching high temperatures due to the failure of the cooling system.
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).	During surgery, the illumination system cable melted, creating smoke and heat and causing the system to stop functioning.
2706	Smoking	Issue associated with a cloud of vapour or gas generated from the device, generally associated after a fire or a burn.	Smoke came out of the main power supply of an IVD auto analyser.
2801	Device Displays Incorrect Message	Issue associated with a device prompting the user with incorrect information in order to indicate a device problem.	Issue associated with a device where the display shows incorrect information about a 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.	Electrode pads connected to an EKG (electrocardiogram) machine were difficult to attach to the patient.
2803	Misassembled	Issue associated with the use of the device characterized by incorrect assembly of device components, parts or constituents.	An adult anaesthesia circuit kit could not be used since it contained an incorrect y-piece and the pressure line was also missing.
2804	Therapy Delivered to Incorrect Body Area	Issue associated with energy delivered to an incorrect body area.	A neurostimulator provided stimulation to the wrong body location due to the migration of the lead away from the intended treatment area.

Level 2 code	Level 2 term	Level 2 definition	Example(s)
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.	Ophthalmic instruments were not properly cleaned prior to steam sterilization and resulted in inadequate sterilization.
2902	Inadequate Training	Issue associated with facility not providing satisfactory initial or periodic user training covering operation of the device.	Healthcare personnel were required to use a device without prior training and that resulted in misuse.
2903	Maintenance Issue	Issue associated with the servicing of a device.	Failure to perform required disinfections of the water system of a dialysis machine resulted in a pyrogenic outbreak.
2904	Refurbishing Issue	Issue associated with the refurbishing of a device.	A third party refurbished an endoscope but did not replace a critical component, causing the device to fail.
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.	Personnel used a device in a way that was in conflict with information delivered through training and in the manufacturer's labelling, including the instructions for use.
2906	Device Inoperable	Issue associated with the device being in a non-functional or inoperable state.	When the defibrillator was turned on, it showed the self-test screen and then locked up.

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