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Robots and robotic devices — Safety requirements for personal care robots

Robots et composants robotiques — Exigences de sécurité pour les robots de soins personnels

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 184, *Automation systems and integration*, Subcommittee SC 2, *Robots and robotic devices*.

Introduction

This International Standard has been developed in recognition of the particular hazards presented by newly emerging robots and robotic devices for new applications in non-industrial environments for providing services rather than manufacturing applications in industrial applications. This International Standard focuses on the safety requirements for personal care robots in non-medical applications.

This International Standard complements ISO 10218-1, which covers the safety requirements for robots in industrial environments only. This International Standard includes additional information in line with ISO 12100 and adopts the approach proposed in ISO 13849 and IEC 62061 to formulate a safety standard for robots and robotic devices in personal care to specify the conditions for physical human-robot contact.

This International Standard is a type-C standard, as stated in ISO 12100.

When a type-C standard deviates from one or more technical provisions dealt with by type-A or by type-B standards, the type-C standard takes precedence.

It is recognized that robots and robotic devices in personal care applications require close human-robot interaction and collaborations, as well as physical human-robot contact.

The robots or robotic devices concerned, and the extent to which hazards, hazardous situations or hazardous events are covered, are indicated in the scope of this International Standard.

Hazards are well recognized, and the sources of the hazards are frequently unique to particular robot systems. The number and types of hazards are directly related to the nature of the robot application, the complexity of the installation, and the level of human-robot interaction incorporated.

The risks associated with these hazards vary with the type of robot used and its purpose, and the way in which it is installed, programmed, operated, and maintained.

Not all of the hazards identified by this International Standard apply to every personal care robot, nor will the level of risk associated with a given hazardous situation be the same from robot to robot. Consequently, the safety requirements, and/or protective measures can vary from what is specified in this International Standard. A risk assessment is conducted to determine the protective measures needed when they do not meet safety requirements and/or protective measures specified in this International Standard, and for the particular application being considered.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

In recognition of the variable nature of hazards with personal care robot applications, this International Standard provides guidance for the assurance of safety in the design and construction of the non-medical personal care robot, as well as the integration, installation, and use of the robots during their full life cycle. Since safety in the use of personal care robots is influenced by the design of the particular robot system, a supplementary, though equally important, purpose is to provide guidelines for the information for use of personal care robots and robotic devices.

The safety requirements of this International Standard have to be met by the manufacturer and the supplier of the personal care robot.

Future editions of this International Standard might include more specific requirements on particular types of personal care robots, as well as more complete numeric data for different categories of people (e.g. children, elderly persons, pregnant women).

Robots and robotic devices — Safety requirements for personal care robots

1 Scope

This International Standard specifies requirements and guidelines for the inherently safe design, protective measures, and information for use of personal care robots, in particular the following three types of personal care robots:

— mobile servant robot;

— physical assistant robot;

— person carrier robot.

These robots typically perform tasks to improve the quality of life of intended users, irrespective of age or capability. This International Standard describes hazards associated with the use of these robots, and provides requirements to eliminate, or reduce, the risks associated with these hazards to an acceptable level. This International Standard covers human-robot physical contact applications.

This International Standard presents significant hazards and describes how to deal with them for each personal care robot type.

This International Standard covers robotic devices used in personal care applications, which are treated as personal care robots.

This International Standard is limited to earthbound robots.

This International standard does not apply to:

— robots travelling faster than 20 km/h;

— robot toys;

— water-borne robots and flying robots;

— industrial robots, which are covered in ISO 10218;

— robots as medical devices;

— military or public force application robots.

NOTE The safety principles established in this International Standard can be useful for these robots listed above.

The scope of this International Standard is limited primarily to human care related hazards but, where appropriate, it includes domestic animals or property (defined as safety-related objects), when the personal care robot is properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.

This International Standard is not applicable to robots manufactured prior to its publication date.

This International Standard deals with all significant hazards, hazardous situations or hazardous events as described in Annex A. Attention is drawn to the fact that for hazards related to impact (e.g. due to a collision) no exhaustive and internationally recognized data (e.g. pain or injury limits) exist at the time of publication of this International Standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2631 (all parts), *Mechanical vibration and shock — Evaluation of human exposure to whole-body vibration*

ISO 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 3864-1, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

ISO 4413, *Hydraulic fluid power — General rules and safety requirements for systems and their components*

ISO 4414, *Pneumatic fluid power — General rules and safety requirements for systems and their components*

ISO 4871, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 8373:2012, *Robots and robotic devices — Vocabulary*

ISO 11202, *Acoustics — Noise emitted by machinery and equipment — Determination of emission sound pressure levels at a work station and at other specified positions applying approximate environmental corrections*

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO 13849-1, *Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design*

ISO 13850, *Safety of machinery — Emergency stop — Principles for design*

ISO 13854, *Safety of machinery — Minimum gaps to avoid crushing of parts of the human body*

ISO 13855[1)], *Safety of machinery — Positioning of safeguards with respect to the approach speeds of parts of the human body*

ISO 13856 (all parts), *Safety of machinery — Pressure-sensitive protective devices*

ISO 13857, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs*

ISO 14118, *Safety of machinery — Prevention of unexpected start-up*

ISO 14119, *Safety of machinery — Interlocking devices associated with guards — Principles for design and selection*

ISO 14120, *Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards*

ISO 15534 (all parts), *Ergonomic design for the safety of machinery*[1]

IEC 60204-1:2009, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements*

IEC 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements*

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1) If used, consideration shall be given as to the relevance and applicability of the quantitative data to the intended users of the robot, especially for elderly people and children.

IEC 60335-2-29, *Household and similar electrical appliances — Safety — Part 2-29: Particular requirements for battery chargers*

IEC 60417-1, *Graphical symbols for use on equipment — Part 1: Overview and application*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 60825-1, *Safety of laser products — Part 1: Equipment classification and requirements*

IEC 61140, *Protection against electric shock — Common aspects for installation and equipment*

IEC 61496 (all parts), *Safety of machinery — Electro-sensitive protective equipment*

IEC 62061:2012, *Safety of machinery — Functional safety of safety-related electrical, electronic and programmable electronic control systems*

IEC 62471, *Photobiological safety of lamps and lamp systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12100, ISO 8373 and the following apply.

3.1
autonomy
ability to perform intended tasks based on current state and sensing, without human intervention

[SOURCE: ISO 8373:2012, 2.2]

3.2
robot
actuated mechanism programmable in two or more axes with a degree of *autonomy* (3.1) moving within its environment, to perform intended tasks

[SOURCE: ISO 8373:2012, 2.6, modified]

3.3
robotic device
actuated mechanism fulfilling the characteristics of an industrial robot or a *service robot* (3.4), but lacking either the number of programmable axes or the degree of *autonomy* (3.1)

[SOURCE: ISO 8373:2012, 2.8, modified]

3.4
service robot
robot (3.2) that performs useful tasks for humans or equipment excluding industrial automation applications

[SOURCE: ISO 8373:2012, 2.10, modified]

3.5
mobile robot
robot (3.2) able to travel under its own control

[SOURCE: ISO 8373:2012, 2.13, modified]

3.6
hazard
potential source of harm

[SOURCE: ISO 12100:2010, 3.6, modified]

3.7
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 12100:2010, 3.12]

3.8
risk assessment
overall process comprising a risk analysis and a risk estimation

[SOURCE: ISO 12100:2010, 3.17, modified]

3.9
safe state
condition of a *personal care robot* (3.13) where it does not present an impending *hazard* (3.6)

[SOURCE: ISO 10218-2:2011, 3.11, modified]

3.10
safety-related part of a control system
part of a control system that responds to safety-related input signals and generates safety-related output signals

[SOURCE: ISO 13489-1:2006, 3.1.1, modified]

3.11
verification
confirmation through the provision of objective evidence that the specified requirements of the *personal care robot* (3.13) have been fulfilled

[SOURCE: ISO 9000:2005, 3.8.4, modified]

3.12
validation
confirmation through the provision of objective evidence that the requirements for specific intended use or application of the *personal care robot* (3.13) have been fulfilled

[SOURCE: ISO 9000:2005, 3.8.5 modified]

3.13
personal care robot
service robot (3.4) that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications

Note 1 to entry: This might include physical *contact* (3.19.1) with the human to perform the task.

Note 2 to entry: Typical types of personal care robots include: *mobile servant robot* (3.14), *physical assistant robot* (3.15) and *person carrier robot* (3.16).

3.14
mobile servant robot
personal care robot (3.13) that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information

3.15
physical assistant robot
personal care robot (3.13) that physically assists a *user* (3.26) to perform required tasks by providing supplementation or augmentation of personal capabilities

3.15.1
restraint type physical assistant robot
physical assistant robot (3.15) that is fastened to a human during use

EXAMPLE This includes wearable suits or non-medical physical assistance exoskeletons.

3.15.2
restraint-free type physical assistant robot
physical assistant robot (3.15) that is not fastened to a human during use

Note 1 to entry: This allows free holding/releasing of the robot by the human in order to control or stop the physical assistance. Examples include power assisted devices and/or powered walking aids.

3.16
person carrier robot
personal care robot (3.13) with the purpose of transporting humans to an intended destination

Note 1 to entry: It might possess a cabin and might be equipped with a seat and/or standing support (or similar).

Note 2 to entry: In addition to humans, transportation might include other objects, e.g. pets and property.

3.17
protective stop
interruption of operation that allows an orderly cessation of motion for safeguarding purposes

3.18.1
maximum space
volume which can be swept by the moving parts of the *robot* (3.2) as defined by the manufacturer, plus the volume which can be swept by manipulators and payloads

Note 1 to entry: For mobile platforms, this volume can be defined by the physical boundaries through which the robot can move around.

Note 2 to entry: See Figure 1.

3.18.2
restricted space
portion of the *maximum space* (3.18.1) confined by limiting devices that establish boundaries which will not be exceeded by the *robot* (3.2)

Note 1 to entry: For *mobile robots* (3.5), this volume can be limited by special markers on floors and walls, or by *software limits* (3.27) defined in the internal map of the robot or facility (maximum space).

Note 2 to entry: See Figure 1.

[SOURCE: ISO 8373:2012, 4.8.2, modified]

3.18.3
monitored space
space observed by sensors available to the *personal care robot* (3.13) in which a *safety-related object* (3.21.1) is detected

Note 1 to entry: Monitored space can reach beyond the *maximum space* (3.18.1) and can be defined by a collection of mobile sensors on the robot and stationary sensors in and outside the maximum space.

Note 2 to entry: This space can be static or dynamic depending on the personal care robot and its application.

Note 3 to entry: See Figure 1.

3.18.4
safeguarded space
space in which the *personal care robot* (3.13) initiates a safety-related function if a *safety-related object* (3.21.1) is detected within it

Note 1 to entry: Examples of safety-related functions include trajectory changes, speed reduction, *protective stop* (3.17), force limiting.

Note 2 to entry: Annex C provides more details on possible implementations of algorithms for the speed reduction.

Note 3 to entry: Space can be static or dynamic, depending on the personal care robot, its application and its (dynamic) shape.

Note 4 to entry: See Figure 1.

3.18.5
protective stop space
space in which the *personal care robot* (3.13) will perform a *protective stop* (3.17) if a *safety-related object* (3.21.1) enters it

EXAMPLE Examples of operational spaces for some different personal care robots are presented in Annex B.

Note 1 to entry: Space can be static or dynamic, depending on the personal care robot, its application and its (dynamic) shape.

Note 2 to entry: See Figure 1.

3.19.1
contact
zero distance between *robot* (3.2) and an object in its external environment

3.19.2
non-contact sensing
detection or measurement capability that does not require touching objects (including humans) in the environment

3.19.3
contact sensing
detection or measurement capability that requires touching objects (including humans) in the environment

3.19.4
unintended contact
unplanned touching between *personal care robot* (3.13) and object while performing the intended task

3.19.5
allowed contact
any touching with the *personal care robot* (3.13) that is permitted by the manufacturer

3.20
relative speed
magnitude of the difference between the velocity vectors of the *robot* (3.2) and an object (including a human) about to be touched

Note 1 to entry: The robot velocity is the vector sum of velocities of the robot body and its moving parts.

3.21.1
safety-related object
human, domestic animal, or property to be protected from harm

Note 1 to entry: The kinds of domestic animals (especially pets) and property to be protected depends on the intended use of the personal care robot.

3.21.2
safety-related obstacle
object, obstacle, or ground condition which can cause harm if it comes into contact or collision with the *robot* (3.2)

3.21.3
safety-related speed limit
upper boundary of speed that a certain point (body location) of a *personal care robot* (3.13) may reach without creating an unacceptable *risk* (3.7)

Note 1 to entry: In the definition, speed can be absolute or relative to the point of interest.

3.21.4
safety-related force limit
upper boundary of force that a certain point of a *personal care robot* (3.13) can exert against a human, or other surrounding objects without creating an unacceptable *risk* (3.7)

3.21.5
safety-related surface condition
surface condition
adverse conditions of travel surface for a mobile *personal care robot* (3.13), for which *hazards* (3.6) can be identified in the *risk assessment* (3.8)

EXAMPLE Surface conditions by which a *person carrier robot* (3.16) might roll over or slip causing injury or damage.

3.22
manual control device
human operated device connected into the control circuit used for controlling the *personal care robot* (3.13)

[SOURCE: IEC 60204-1:2009, 3.9, modified]

Note 1 to entry: One or more manual control devices attached to a panel or housing form a *command device* (3.23).

3.23
command device
device that enables the *operator* (3.25) or a *user* (3.26) to control the *robot* (3.2)

3.24.1
manual mode
operational mode in which the *robot* (3.2) is operated by direct human intervention via, for example, pushbuttons or a joystick

Note 1 to entry: This mode is usually used for teaching, tele-operation, fault-finding, repair, cleaning, etc.

[SOURCE: ISO 8373:2012, 5.3.10.2, modified]

3.24.2
autonomous mode
operational mode in which the *robot* (3.2) function accomplishes its assigned mission without direct human intervention

EXAMPLE *Mobile servant robot* (3.14) waiting for an interaction (a command).

3.24.3
semi-autonomous mode
operational mode in which the *robot* (3.2) function accomplishes its mission with partial human intervention

EXAMPLE *Physical assistant robot* (3.15) that tries to correct the human-chosen path to avoid collisions.

3.25
operator
person designated to make parameter and program changes, and to start, monitor, and stop the intended operation of the *personal care robot* (3.13)

[SOURCE: ISO 8373, 2.17, modified]

3.26
user
either the *operator* (3.25) of the *personal care robot* (3.13) or the beneficiary of the service provided by the personal care robot

Note 1 to entry: In some applications, a user could be both the operator and the beneficiary.

3.27
software limits
restrictions to one or more operational parameters of the *robot* (3.2) defined in the control system

Note 1 to entry: Software limit can restrict operating spaces, speed, force, etc.

3.28
singularity
occurrence whenever the rank of the Jacobian matrix becomes less than full rank

Note 1 to entry: Mathematically, in a singular configuration the joint velocity in joint space might become infinite to maintain Cartesian velocity. In actual operation, motions defined in Cartesian space that pass near singularities can produce high axis speeds which can lead to hazardous situations.

Note 2 to entry: The Jacobian matrix is typically defined as a matrix of the first order partial derivatives of the robot's degrees of freedom.

[SOURCE: ISO 10218-1:2011, 3.22, modified]

3.29
electro-sensitive protective equipment
ESPE
assembly of devices and/or components working together for protective tripping or presence-sensing purposes, and comprising as a minimum

— a sensing device;

— controlling/monitoring devices;

— output signal switching devices and/or a safety-related data interface

Note 1 to entry: The safety-related control system associated with the ESPE, or the ESPE itself, might further include a secondary switching device, muting functions, stopping performance monitor, etc.

Note 2 to entry: A safety-related communication interface can be integrated in the same enclosure as the ESPE.

[SOURCE: IEC 61496-1:2004, 3.5, modified]

3.30
pressure-sensitive protective equipment
PSPE
assembly of devices and components triggered using the "mechanical activated trip" method to provide protection under hazardous situations

Note 1 to entry: Examples of PSPE are pressure sensitive mats and floors, bumpers, pressure sensitive edges and bars.

Note 2 to entry: PSPE generate a stopping signal by the use of different techniques, e.g. mechanical contacts, fibre-optic sensors, pneumatic sensors.

4 Risk assessment

4.1 General

For risk assessment all requirements of ISO 12100 shall apply. This provides requirements and guidance in performing risk assessment, including risk analysis based on hazard identification. In performing the risk assessment, the decision of whether a risk is acceptable or not depends on the application and the intended use of the personal care robot.

ISO 12100 includes general lists of hazards for machinery, from which the list of hazards for personal care robots presented in Annex A is derived.

4.2 Hazard identification

The hazard identification shall be carried out to identify any hazards that might be present in a particular personal care robot. Annex A contains a list of typical hazards that can be present with the personal care robots described in this International Standard. This list should not be considered all-inclusive and specific personal care robot systems might also present other hazards as a result of their particular design, intended use or reasonably foreseeable misuse. An application hazard identification process shall be performed for each design, and shall give particular consideration to:

a) uncertainty of autonomous decisions made by the robot and possible hazards from wrong decisions;

b) different levels of knowledge, experience and physical conditions of users and other exposed persons;

c) normal but unexpected movement of the personal care robot;

d) unexpected movement (e.g. jumping in front of the personal care robot from the side or from a higher level) of humans, domestic animals and other safety-related objects;

e) unintended movement of the personal care robot;

f) unexpected travel surfaces and environmental conditions in the case of mobile robots;

g) uncertainty of safety-related objects to be handled in the case of mobile servant robots;

h) conformity to the human anatomy and its variability in the case of physical assistant robots and person carrier robots.

Where appropriate, the risk assessment shall consider in particular, manipulators and end-effectors of the personal care robot, and they shall be given the same requirements as for the robots.

4.3 Risk estimation

A risk estimation shall be carried out on those hazards identified under 4.2, with careful attention paid to various situations where the personal care robot may contact safety-related objects.

After all inherently safe design and protective measures have been adopted, the residual risk of the personal care robot shall be evaluated and proven that it is reduced to an acceptable level.

Appropriate risk estimation methods shall be designed, on a case-by-case basis. The results of the estimation shall be drawn upon to show that the event (e.g. allowed contact between a robot and safety-related obstacles, or other safety-related objects), does not cause any unacceptable risk. If numeric values for risk assessment are used for specific applications, an appropriate validation of the test/measurement methodology shall be provided. If numeric values from other sources are used for risk estimation, it shall be validated that referring to them is appropriate.

NOTE 1 Human-robot interaction and impacts research studies have been carried out on pain tolerance limits of adults and robot-human collisions on various parts of the human body to study significant injury mechanisms (see Bibliography).