

BS EN ISO 13482:2014



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Robots and robotic devices — Safety requirements for personal care robots

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National foreword

This British Standard is the UK implementation of EN ISO 13482:2014.

The UK participation in its preparation was entrusted to Technical Committee AMT/-/2, Robots and robotic devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Robots et composants robotiques - Exigences de sécurité pour les robots de soins personnels (ISO 13482:2014)

Roboter und Robotikgeräte - Sicherheitsanforderungen für nicht-industrielle Roboter - Nichtmedizinische Haushalts- und Assistenzroboter (ISO 13482:2014)

This European Standard was approved by CEN on 4 January 2014.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 13482:2014) has been prepared by Technical Committee ISO/TC 184 “Automation systems and integration” in collaboration with Technical Committee CEN/TC 310 “Advanced automation technologies and their applications” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2014, and conflicting national standards shall be withdrawn at the latest by August 2014.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13482:2014 has been approved by CEN as EN ISO 13482:2014 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 2006/42/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 2006/42/EC *Machinery safety*.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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Foreword

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

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 13855¹⁾, *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*

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).

NOTE 2 More complete numeric data for different categories of people (e.g. children, elderly persons, pregnant women) and personal care robot application (e.g. mobile servant, physical assistant, person carrier) are being determined and will be included in a future edition of this International Standard. Some work in this direction has commenced for industrial robots, which will be published as ISO/TS 15066²⁾ to assist in the design of workplaces with collaborative robots.

5 Safety requirements and protective measures

5.1 General

Personal care robots shall conform to the safety requirements of this clause. Once the hazards associated with a personal care robotic application have been identified using the methods described in [Clause 4](#), the robot shall be designed to ensure that the risk from those hazards is below a tolerable level. In addition, the machine shall be designed according to the principles of ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document.

When risks can be eliminated or reduced by measures that are not described in this International Standard, other requirements shall be applied as determined by risk assessment. These measures shall achieve at least the same level of risk reduction as the measures described in this International Standard.

Measures shall be taken to protect any exposed person and, where relevant, any domestic animal or other safety-related objects near the personal care robot from any hazards, and to ensure the user's safety for continuous use of the robot as much as reasonably practicable.

Personal care robots might need to adhere to additional standards and regulations, where appropriate, e.g. motor vehicle regulations when person carrier robots are operating on public roads.

A personal care robot shall be designed according to the principles of ISO 12100 for all hazards identified for its application, comprising the following:

- a) inherently safe design;
- b) protective measures;
- c) information for use.

NOTE ISO 12100 is indispensable for the application of this International Standard. It is advisable that users are familiar with ISO 12100 before they apply or use this International Standard.

The use of inherently safe design measures is the first and most important step in the risk reduction process because such inherent characteristics of the personal care robot are likely to remain effective, whereas experience has shown that even well-designed safeguarding measures can fail or be violated, and information for use may not be followed.

Inherently safe design measures avoid hazards by reducing or eliminating risks through a suitable choice of design features of the personal care robot itself, and/or interaction between the exposed persons and the robot. Requirements for inherently safe design measures are provided in subclauses 5.x.2 or 5.x.x.2 of each subclause 5.x or 5.x.x respectively.

Adding safeguards, and/or protective measures is the second step of the risk reduction method. As a large number of risks arise due to the possible dynamic interactions between safety-related obstacles and the personal care robot, a protective control function of the robot might significantly reduce a particular type of risk. Requirements for protective measures are provided in subclauses 5.x.3 or 5.x.x.3 of each subclause 5.x or 5.x.x respectively.

When risk reduction is achieved by the use of safety-related control functions, the requirements of [Clause 6](#) apply.

2) Under preparation.

Information about the residual risks, after inherently safe design and protective measures have been incorporated, shall be provided in the instruction handbook. Specific requirements regarding information for use for each hazard are provided at subclause 5.x.4 or 5.x.x.4 of each subclause 5.x or 5.x.x (respectively) whereas general requirements regarding information for use are provided in [Clause 8](#).

The satisfaction of the safety requirements of this clause can be verified by one or more methods, such as:

- A: inspection;
- B: practical tests;
- C: measurement;
- D: observation during operation;
- E: examination of circuit diagrams;
- F: examination of software;
- G: review of task-based risk assessment;
- H: examination of layout drawings and relevant documents.

Recommended methods of verification and validation of various requirements for the significant hazards are shown in subclause 5.x.5 or 5.x.x.5 of each subclause 5.x or 5.x.x (respectively) at the end of each clause, in the form of which of the methods (A, B, etc.) are applicable, corresponding to the methods listed above. A description of the verification and validation methods is given in [Clause 7](#).

5.2 Hazards related to charging battery

5.2.1 General

If a personal care robot has an integrated and built-in battery charging system, persons shall be protected against hazards due to accidental contact with the charging connections on the robot and its charging systems, which shall be in compliance with IEC 60204-1 or IEC 60335-2-29 as appropriate, and should be in compliance with IEC 60529 and EN 50272.

Also the charging system shall prevent any hazards arising because of overloading or charging of deeply discharged batteries.

5.2.2 Inherently safe design

Charging contacts and plugs shall be designed in a way that accidentally touching live parts is prevented (e.g. caps for plugs and outlets).

Voltage between charging contacts shall conform to appropriate standard according to the application and/or environment of the charging systems, such as IEC 60204-1, IEC 61140, IEC 60335-2-29 and IEC 61851.

Battery charging currents shall be chosen to be as low as reasonably practicable.

5.2.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

- a) charging systems shall be designed in such a way that the charging connections are only activated when the personal care robot is connected to them;
- b) charging systems shall display the charging status or give a signal when the battery is fully charged;

- c) charging systems shall be designed in such a way that the correct charging of the battery is automatically supervised, and thus hazards caused by overloading or charging of deeply discharged batteries are prevented.

5.2.4 Information for use

Information for use shall contain instructions for battery charging, in particular:

- the procedure for charging the personal care robot;
- the environmental conditions (e.g. outdoor or indoor charging);
- requirement to switch the personal care robot off, or into a certain operational mode;
- appropriate warnings.

5.2.5 Verification and validation

Appropriate method(s) shall be chosen from the following: B, C, D, E.

5.3 Hazards due to energy storage and supply

5.3.1 Contact with hazardous energy parts

5.3.1.1 General

A personal care robot shall be designed and constructed so that all hazards related with its energy are prevented.

The personal care robot's electrical equipment shall be designed and constructed in compliance with the relevant requirements of IEC 60204-1 for electrical equipment, of ISO 4414 for pneumatic equipment and of ISO 4413 for hydraulic equipment.

Any exposed person shall be protected from direct or indirect contact with live parts on the robot.

A means of isolating any hazardous energy sources (e.g. electrical, mechanical, hydraulic, pneumatic, chemical and thermal) shall be provided. Such hazardous energy sources shall be clearly identified, and the isolators shall be capable of being locked if reconnection leads to a hazard.

5.3.1.2 Inherently safe design

The following measures shall be applied where appropriate:

- a) use of safe extra-low voltage sources for electrical equipment according to IEC 61140 (below 25 V AC and 60 V DC);
- b) use of low pressures for pneumatic/hydraulic equipment.

Other types of stored energy shall be kept to a level as low as reasonably practicable, to minimize the hazard.

5.3.1.3 Safeguarding and complementary protective measures

Where guards or enclosures are used to protect from hazardous energy parts, their design shall conform to appropriate IP class as defined in IEC 60529 for electrical hazards and safety distances of ISO 13857 for other hazards as determined by risk assessment.

Where excessive heat is present, heat dissipation measures shall be applied (e.g. heat sinks, air flow). If fans are used, fan control devices are recommended.

5.3.1.4 Information for use

Warning markings shall be put on the personal care robot complying with ISO 7010, and their meaning shall be explained in the information for use.

5.3.1.5 Verification and validation

Appropriate method(s) shall be chosen from the following: A, B, C, E, H.

5.3.2 Uncontrolled release of stored energy

5.3.2.1 General

Uncontrolled release of stored energy shall not lead to hazard. This applies while the robot is operating as well as when the robot is switched off.

A means shall be provided for the controlled release or removal of stored hazardous energy. The controlled release or removal of stored energy shall not lead to any additional hazard.

NOTE Stored energy can occur in pneumatic and hydraulic pressure accumulators, capacitors, batteries, springs, counter balances, flywheels, etc.

5.3.2.2 Inherently safe design

Stored energy shall be kept to a level as low as reasonably practicable.

5.3.2.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

- a) guards/covers shall be applied to minimize the risk during any release of energy;
- b) the robot shall be provided with the means to regulate its energy supply so as to prevent overheating or over-currents caused by overloads, short circuits, clothes which encompass the heat source of the robot, or device malfunction.

5.3.2.4 Information for use

Labels shall be affixed to identify all the stored energy hazards and their locations. Information for use shall contain the description of the means, and the procedures for the removal or controlled release of stored energy.

5.3.2.5 Verification and validation

Appropriate method(s) shall be chosen from the following: B, D, E, H.

5.3.3 Power failure or shutdown

5.3.3.1 General

Power failure or unintended shutdown of a personal care robot and subsequent re-application of power shall not lead to unacceptable risk. Special consideration shall be taken to ensure the following.

- a) Personal care robots equipped with manipulators shall be designed to ensure that the risks due to manipulator movement or dropped loads in the event of failure or shutdown of power to the manipulator are acceptable. This shall be achieved regardless of the type(s) of power supply (e.g. electrical, hydraulic, pneumatic, vacuum).

- b) Personal care robots equipped with mobile platforms shall be designed to ensure that the risks due to robot travel following failure or shutdown of power (e.g. runaway) are acceptable. This shall be achieved regardless of the robot locomotion mechanisms (e.g. wheels, tracks, legs).
- c) A personal care robot that is capable of cutting its actuation power off temporarily shall be designed to ensure that the risks due to robot parts or components being dropped are acceptable in case of power loss or change.
- d) Where practicable, if a part of a personal care robot presents a trapping hazard, means shall be provided to move this part without drive power by a single person. This shall take into account the full range of potential users to allow their escape or rescue, as determined by risk assessment. If this is not possible, a complementary safe guarding measure shall be applied.

NOTE IEC 60204-1 gives requirements for electrical power supply.

5.3.3.2 Inherently safe design

The following measures shall be applied where appropriate:

- a) use of the “de-energize to apply” principle in the design of braking mechanisms of all moving parts;
- b) internal storage of sufficient energy to allow recovery to a safe state following power failure/shutdown.

To avoid an unexpected start-up, the requirements of ISO 14118 shall be met.

5.3.3.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

- a) means to provide an uninterruptable power source shall be made;
- b) personal care robots able to trap humans in isolated locations shall be provided with a means of summoning assistance powered independently;
- c) in case the available internal energy or stored power (e.g. battery power) falls below a certain threshold, the robot shall notify its status to the user and/or operator by means such as audio, light, vibration indications, and shall come into a safe state automatically in case the battery power reaches a hazardous level.

5.3.3.4 Information for use

The information for use shall describe the residual risks relevant to power failure or shutdown. Maintenance procedures can be required following such power failures or shutdowns, if deemed necessary by risk assessment (see [8.4](#)).

5.3.3.5 Verification and validation

Appropriate method(s) shall be chosen from the following: B, D, E, H.

5.4 Robot start-up and restart of regular operation

5.4.1 General

Personal care robots shall not perform any hazardous action immediately upon start up.

5.4.2 Inherently safe design

The following measures shall be applied where appropriate.

- a) During start-up the personal care robot shall perform internal control tests to ensure that all safety-related functions are available. Failure to do so shall avoid any hazardous operation.
- b) If the personal care robot's safety-related functions cannot be performed correctly after start up, then it shall immediately perform a protective stop.
- c) The personal care robot shall start up in a state of restricted speed, force, etc. (see [6.4](#) and [6.7](#)) and shall only return to normal levels of control by means of a mode change (see [6.11](#)).
- d) The personal care robot shall always start up in manual mode, and shall only continue operation in autonomous mode by means of a mode change as specified in [6.11.1](#).

If testing of some safety-related components requires robot motion, the minimum motion necessary to establish the absence of faulty safety-related components is allowed. The risks associated with this motion shall be kept as low as reasonably practicable.

5.4.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate.

- a) Manipulators, mobile platforms and other moving parts shall be de-activated by safety-related functions at start-up (to prevent any unintended actions). Application functions shall only be enabled if it can be positively established, via sensors, that no hazardous situation exists. This measure shall be applied if the robot is intended to enter autonomous mode immediately after start-up.
- b) The personal care robot shall always start up in a monitored standstill and shall only return to normal operation by means of a user action.

5.4.4 Information for use

Necessary start-up and restarting instructions shall be provided in the robot's information for use according to the measures which have been applied.

5.4.5 Verification and validation

Appropriate method(s) shall be chosen from the following: B, D, F.

5.5 Electrostatic potential

5.5.1 General

The personal care robot shall be designed to avoid all harm to humans and domestic animals caused by electrostatic potential and discharge.

Electrostatic discharge (ESD) protection shall be sufficient that no personal protective equipment is required by users.

Any build-up of harmful electrostatic potential shall be discharged.

The personal care robot shall be designed to avoid harmful malfunction due to electrostatic potential discharge.

NOTE IEC 61000-4-2 gives additional guidance (see also [5.6](#)).

5.5.2 Inherently safe design

The following measures shall be applied where appropriate:

- a) use of conductive materials;
- b) discharging of outer surfaces by earthing;
- c) other techniques to prevent build-up of electrostatic charge on surfaces or parts that can be touched.

5.5.3 Safeguarding and complementary protective measures

Use of covers of the electrical equipment shall be in compliance with IEC 60204-1 to avoid contact with live parts.

5.5.4 Information for use

Necessary relevant warning signs for ESD from ISO 7010 shall be provided together with the information for use.

5.5.5 Verification and validation

Appropriate method(s) shall be chosen from the following: B, C, E.

NOTE IEC 61000-4-2 and ISO 7176-21 contain applicable test methods.

5.6 Hazards due to robot shape

5.6.1 General

Intended use case scenarios to perform intended tasks by the personal care robot shall be considered in the design of the overall shape of the robot, and of its external parts, to avoid the potential for accidents that could cause, for example, crushing, cutting, or severing injuries.

Risk assessment shall also consider the shape of load being carried by the personal care robot.

EXAMPLE Exoskeleton straps shall be designed not to cause injuries, e.g. cutting or abrasion.

5.6.2 Inherently safe design

Sharp edges and points shall be avoided in the design of the personal care robot, according to ISO 12100.

Holes or gaps in the accessible part of the robot shall be designed so that the insertion of any part of the human body is prevented, in compliance with ISO 13854 and ISO 15534.

The robot's joints (e.g. those in the manipulator) shall be designed in a way that parts of the human body cannot be crushed when the joint is moved as intended by the manufacturer. This can be done by choosing the robot geometry as well as by restricting the joint limits inherently.

Limiting the load being carried to objects which are not sharp or pointed.

5.6.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

- a) cushioning on sharp edges and points shall be provided to eliminate shearing, stabbing, cutting hazards and reduce impact hazards (see [4.3](#), Note 2);
- b) use of fixed or movable guards to cover hazardous moving parts;

- c) adjustment of the robot speed and behaviour, if hazardous loads (e.g. sharp or pointed objects) are being carried.

5.6.4 Information for use

Warnings and instructions mitigating shape-related risks shall conform to ISO 12100 and ISO 7010.

The information for use shall contain instructions for protective equipment (e.g. gloves) needed for handling, using, or operating, etc., the personal care robot.

Where the shape of load being carried can lead to additional hazards, appropriate instructions to deal with these risks shall be given.

5.6.5 Verification and validation

Appropriate method(s) shall be chosen from the following: A, C, G, H.

5.7 Hazards due to emissions

5.7.1 Hazardous noise

5.7.1.1 General

Any human near the personal care robot shall be protected from noise (including ultrasonic noise) that could directly cause discomfort, stress, hearing loss, loss of balance or consciousness of the user, or similar disorders arising from the robot's operation.

The level of acoustic noise emitted by the personal care robot shall be sufficiently low that no special protective equipment needs to be worn.

The personal care robot shall conform to noise emission standards appropriate to its intended purpose (e.g. see ISO 1996, ISO 3740, ISO 11200, ISO/TS 15666, ISO 15667).

NOTE Acoustic environmental noise assessment can be found in ISO 1996-1 and ISO 1996-2.

5.7.1.2 Inherently safe design

ISO/TR 11688-1 gives general technical information and guidance for the design of low-noise machines. Special care shall be taken in the acoustical design of the robot. The following measures shall be applied where appropriate:

- a) low-noise component: the personal care robot shall be constructed with components which are inherently silent in their operation;
- b) appropriate operational behaviour: robot actions and/or motions shall be designed to be as quiet as practicable, given the required tasks of the personal care robot;
- c) sound-damping materials: the personal care robot shall be constructed with materials that limit acoustic noise and reduce its emission to the outside environment.

NOTE ISO/TR 11688-2 gives useful information on noise generation mechanisms in machinery.

5.7.1.3 Safeguarding and complementary protective measures

At least one of the following measures shall be applied:

- a) additional sound absorbing materials, e.g. foam, baffles, curtains, coatings;
- b) use of active noise cancellation (anti-noise) mechanisms.

5.7.1.4 Information for use

Information for use shall list safeguards and protective measures used for noise reduction, and shall give appropriate instructions for maintenance. Where necessary, instructions for regular checks of the emitted noise shall be provided.

5.7.1.5 Verification and validation

Appropriate method(s) shall be chosen from the following: C, D.

The dual-number declaration according to ISO 4871 shall be applied, and the measurement, declaration and verification of noise emission values shall be made according to ISO 3746 or ISO 11202, as appropriate.

5.7.2 Hazardous vibrations

5.7.2.1 General

Personal care robot users shall be protected from harmful indirect or direct vibrations from the robot in use, so that their physical conditions are safeguarded during its operation.

- a) A personal care robot user shall be protected from harmful vibrations that could cause vibration-related injuries, e.g. tendon inflammation, backache, discomfort, neurosis, arthritis, or similar disorders of any kind due to continuous use of the robot.
- b) A personal care robot user shall be protected from vibration between 0,5 Hz and 80 Hz which can cause problems for health, comfort, and perception, and vibration between 0,1 Hz to 0,5 Hz which can cause motion sickness. Personal care robot designs shall conform to all applicable parts of ISO 2631.

The level of vibration from the personal care robot shall be sufficiently low so that no special protective equipment needs to be worn.

5.7.2.2 Inherently safe design

This may include, but not be limited to, the following measures:

- a) minimization of vibration produced by mechanical components in the design of the personal care robot, e.g. by reducing eccentric mass distribution or limiting speed of moving parts;
- b) selection and use vibration damping materials within the design to limit the extent to which humans are exposed to the vibration sources within the personal care robot;

5.7.2.3 Safeguarding and complementary protective measures

At least one of the following measures shall be applied:

- a) application of active vibration control, e.g. by semi-active damping mechanisms or control-based damping;
- b) restriction of the movement of the personal care robot to appropriate velocities which cause no, or minimal, vibration.

5.7.2.4 Information for use

Information for use shall contain specification of the vibrating components.

5.7.2.5 Verification and validation

Appropriate method(s) shall be chosen from the following: C, D.