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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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

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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*

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 15066[2)] 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.

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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 accidently 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 over-heating 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.

5.7.3 Hazardous substances and fluids

5.7.3.1 General

A personal care robot user shall be protected from emissions of any poisonous or noxious materials, or from solvents from the robot body surface or from even within its body if the solvent is highly volatile, which might cause burns or any kind of irritation (e.g. see ISO 14123-1);

The personal care robot shall be designed so that no hazardous substances and fluids are emitted. The robot shall be designed such that during normal operation no protective equipment needs to be worn by the user.

No material that might cause allergies should be used at a surface which comes into contact with human skin during normal use of the personal care robot.

NOTE Nickel, chromium and some types of rubber might cause allergic reactions.

5.7.3.2 Inherently safe design

The following measures shall be applied as appropriate:

a) elimination or avoidance of potentially hazardous substances and fluids, e.g. oil, cooling fluid, and dust arising from brake abrasion within the personal care robot;

b) substitution of potentially hazardous substances and fluids, e.g. oil, cooling fluid, and brake materials by those which are less harmful or non-hazardous;

c) design of the personal care robot to contain substances internally rather than releasing them into the external environment.

5.7.3.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) measures to detect loss of hazardous substances and fluids (e.g. oil) if hazardous substances or fluids are needed for operation;

b) shut-off valves or fuses to seal leaking fluid pipes;

c) measures to prevent humans from touching in case of leakage (e.g. covers).

5.7.3.4 Information for use

Information for use shall be provided about any hazardous substances inside the personal care robot. If necessary instructions for taking precautions during use, handling, maintenance, and disassembly of the robot shall be given.

If allergenic materials are used, the information about the materials shall be provided.

5.7.3.5 Verification and validation

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

5.7.4 Extreme temperatures

5.7.4.1 General

A personal care robot user shall be protected from extreme temperatures (either high or low temperatures) of the robot or its components that might cause burns, chilblains, stress, discomfort, or similar disorders of any kind. To achieve this requirement, the personal care robot shall conform to ISO 13732.

NOTE Surface temperatures between 10 °C and 43 °C are normally not considered to be extreme.

5.7.4.2 Inherently safe design

The following measures shall be applied where appropriate:

a) elimination or avoidance of extreme heat sources within the personal care robot;

b) choosing materials and their textures with appropriate thermal conductivities.

5.7.4.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) reducing (or increasing) the surface temperature with an appropriate cooling (or heating) system;

b) isolation or the application of guards (see ISO 13732).

5.7.4.4 Information for use

Information for use shall contain warnings and markings on the hot/cold parts having extreme temperatures in compliance with ISO 3864-1. If necessary, instructions for taking precautions during use, handling, maintenance and disassembly of the personal care robot shall be given.

5.7.4.5 Verification and validation

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

5.7.5 Hazardous non-ionising radiation

5.7.5.1 General

Emissions by hazardous laser light and other electromagnetic wave sources shall be prevented. Light sources other than lasers shall be designed to not exceed the exposure limit for users, in accordance with IEC 62471.

The use of lasers shall conform to IEC 60825-1, and the lowest possible laser class required by the application shall be used.

5.7.5.2 Inherently safe design

The laser equipment used shall not exceed class 1 according to IEC 60825-1.

5.7.5.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) protective shutters;

b) interlocking movable guards;

c) direction control of laser beams, e.g. avoiding directions where eyes are likely to be according to the requirements in 6.1;

d) controlling laser-power (e.g. pulse duration, intensity) in compliance with 6.1;

e) for lasers of class 2 and higher, the protective measures of IEC 60825-1 shall be met.

5.7.5.4 Information for use

Information for use shall provide details of potentially hazardous emissions likely to be encountered by persons and, where appropriate, domestic animals or property in the operational environments of the personal care robot. The information for use shall advise not to look directly into light, shall give information for personal protective devices and other special behaviour. Also markings on the robot shall be attached, and their meaning shall be described in the information for use.

5.7.5.5 Verification and validation

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

5.7.6 Hazardous ionising radiation

Personal care robot users and third parties shall be protected from ionising radiation emitted by the robot or its components. Exposure to such radiation shall be minimized to avoid any harmful physical injuries or disorders.

Mechanisms producing ionising radiation should not normally be used in any personal care robot. If such a mechanism is essential for the robot's application (i.e. where there is no alternative method of achieving the application objectives) then special protection requirements shall be developed. Special safety protection measures shall be developed in accordance with appropriate standards (e.g. ISO 2919, ISO 3925 and ISO 14152).

5.8 Hazards due to electromagnetic interference

5.8.1 General

For all reasonably foreseeable electromagnetic disturbances, hazardous robot motion and unsafe system states shall be prevented.

The personal care robot shall conform to all relevant standards for EMC (e.g. IEC 61000-6-1, IEC 61000-6-2, IEC 61000-6-3, IEC 61000-6-4 and IEC 60204-1).

NOTE In addition, IEC/TS 61000-1-2 might be useful for providing a methodology for the achievement of functional safety of electrical and electronic systems, including equipment, with regard to electromagnetic phenomena.

5.8.2 Inherently safe design

The functions of the control system described in 6.1 shall be designed to meet the electromagnetic immunity requirements of IEC 62061:2012, 6.4.3.

Other function(s) of the personal care robot should meet IEC 61000-6-1 or IEC 61000-6-2, according to the intended operating environment.

5.8.3 Safeguarding and complementary protective measures

The risk shall be reduced to an acceptable level by electromagnetic shielding against incoming radiation.

5.8.4 Information for use

Information for use shall provide necessary information of the property of the radiating electromagnetic waves as well as the property of the electromagnetic waves which can potentially cause interference.

5.8.5 Verification and validation

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

5.9 Hazards due to stress, posture and usage

5.9.1 General

Hazards can arise from both physical and mental aspects of using the personal care robot. In addition to reducing the individual effects as described in 5.7.2 and 5.7.3, the combined effects shall also be considered in the risk assessment.

5.9.2 Physical stress and posture hazards

5.9.2.1 General

Risk assessment shall identify hazards due to physical stress and posture, and the personal care robot's design shall ensure that any such risk is minimized. This may be achieved by, but may not be limited to, the following requirements:

a) A personal care robot shall be designed to minimize or reduce physical stress or strain to its user due to continuous use, including but not limited to uncomfortable posture, operational environments that would directly cause physical discomfort, e.g. fatigue and tendon inflammation.

b) The design of the personal care robot shall take into account typical body sizes of the intended user population in order to avoid physically demanding body postures or to ensure easy operation. ISO 14738 describes how principles of ergonomic factors, by construction of workstations and machinery, should be applied. This should be considered when building a personal care robot, where somebody sits on or stands in front of the robot.

5.9.2.2 Inherently safe design

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

a) the design and location of manual control devices, which should ensure that they can be operated without physical stress or discomfort;

b) the proper ergonomic design and location of the seat, which should ensure that good posture can be maintained during operation of the personal care robot;

c) command devices that are detachable or hand-held instead of being permanently attached to the personal care robot in an inappropriate position.

5.9.2.3 Safeguarding and complementary protective measures

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

a) use of shock absorbing (suspension) mechanisms;

b) use of posture supports.

5.9.2.4 Information for use

The information for use shall contain instructions about the correct way to operate the manual control devices and how to use the personal care robot. The information for use shall include the need for proper training to avoid operator travel time being longer than recommended.

5.9.2.5 Verification and validation

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

5.9.3 Mental stress and usage hazards

5.9.3.1 General

Risk assessment shall identify hazards due to mental stress and usage, and the personal care robot's design shall ensure that any such risk is minimized. This may be achieved by, but may not be limited to, the following requirements:

a) a personal care robot shall be designed to minimize or reduce mental stress to its user due to continuous use;

b) user interfaces such as controls, signalling or data display elements, shall be designed to be easily understood so that clear and unambiguous interaction between the human and the personal care robot is possible;

c) the personal care robot shall conform to ergonomics standards appropriate to its intended purpose (see ISO/TR 9241-100, ISO 9241-210, ISO 9241-400, ISO 9241-920 and ISO 11228).

5.9.3.2 Inherently safe design

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

a) provision of adequate lighting;

b) designing the personal care robot to avoid the need for sustained attention in order to detect critical signals as far as reasonably practicable or over long periods of time;

c) adequate display design;

d) reduction of signal uncertainty and improvement of detectability.

5.9.3.3 Safeguarding and complementary protective measures

There are no recommended measures for safeguarding with respect to this hazard.

5.9.3.4 Information for use

The information for use shall contain instructions about the correct way to operate the manual control devices and how to use the personal care robot. The information for use shall include the need for proper training where necessary.

5.9.3.5 Verification and validation

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

5.10 Hazards due to robot motion

5.10.1 General

The risk of hazards due to any motion (intended or unintended) of the personal care robot shall be reduced to an acceptable level. Robot components shall be designed, constructed, secured, or contained so that the risks of hazards caused by breaking or loosening are reduced to acceptable levels.

Exposed persons shall be protected from hazardous movement of the personal care robot, e.g. rollovers and runaways, under normal usage and operation of the robot, curves, inclines, and similar operational conditions in its working environment.

5.10.2 Mechanical instability

5.10.2.1 General

Personal care robots shall be designed to have sufficient stability to allow them to be used in their specified conditions of use. Specific stability requirements for particular robot types in particular situations are specified in 5.10.6 and 5.10.7.

The personal care robot shall be designed to minimize mechanical instability (e.g. overturning, falling or excessive leaning when in motion) due to failure or reasonable foreseeable misuse.

The personal care robot shall be designed so that no extraordinary actions or procedures are required by the user in order to maintain its mechanical stability.

Mechanical stability shall not be affected in any phase of the robot's life cycle (including handling, transportation, installation, use, de-commissioning, and dismantling).

The personal care robot shall conform to mechanical stability standards appropriate to its intended purpose (e.g. for mobile personal care robots, see ISO 7176-1 and ISO 7176-2 for static and dynamic stabilities of wheelchairs).

Stability shall be maintained against static and dynamic forces from any moving parts and loads of the personal care robots (e.g. extendible manipulators).

5.10.2.2 Inherently safe design

The following measures shall be applied where appropriate:

a) designing the ground support area to be as large as reasonably practicable;

b) designing the centre of gravity of the personal care robot to be as low as reasonably practicable;

c) designing the personal care robot to ensure that mechanical resonance effects cannot lead to instability;

d) designing the masses of moving parts, especially the manipulator, to be as low as reasonably practicable,

5.10.2.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) use of stability control;

b) means to detect the onset of instability and act (or not) to reduce harm;

c) means to limit the velocity or range of the manipulator;

d) means to prevent overload.

EXAMPLE Tilt sensors, harnesses, roll-bars, feedback control, monitoring and controlling the zero moment point.

Any control systems performing the above functions shall comply with 6.1, in accordance with the robot's risk assessment.

5.10.2.4 Information for use

The information for use shall contain limits of use for the personal care robot concerning slope of travel surface, speed, payload, etc.

5.10.2.5 Verification and validation

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

NOTE For lift chairs, ISO 7176 is applicable, but testing of personal care robots could also include user lift capabilities.

5.10.3 Instability during travel

5.10.3.1 General

A personal care robot capable of travel shall be designed to ensure that it does not cause any hazardous rollovers, runaways, or drops of its body parts or loads being carried during travel. This shall be achieved for all intended travel patterns (e.g. forward/backward travels, rotations, turns/U-turns, accelerations, and decelerations) in its specified operating environments, which is determined depending on its specific application type and design.

For personal care robots whose stabilities vary depending on configurations and loads, maximum speeds and accelerations shall be determined for each intended situation.

For personal care robots that travel autonomously, the control system shall be designed to ensure, as far as reasonably practicable, travel stability under foreseeable conditions.

Any human near the personal care robot shall be protected from the robot falling or rolling over.

Risk assessment shall consider potential hazards due to incorrect positioning of passengers in or on person carrier robots.

5.10.3.2 Inherently safe design

The following measures shall be applied where appropriate:

a) design of the mass distribution within the personal care robot to ensure that the robot cannot fall, rollover or overturn, even when travelling at maximum acceleration/deceleration or turning at maximum speed on the worst case travel surface gradient identified within the intended environment specified for the robot;

b) design of the travel actuators (e.g. wheels, legs/feet) shall ensure that sufficient adhesion with the terrain is maintained over all terrain types, even on slippery surfaces, etc., as defined in the specification of intended environmental conditions for the personal care robot;

c) design of the stability of the personal care robot to ensure that it does not fall, rollover or overturn when travelling over uneven terrain, up to the worst case limits defined within the intended environmental conditions specified for the robot.

5.10.3.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) travel surface sensing as described in 6.5.3;

b) the personal care robot shall be able to plan a travel path to perform its intended task based on environmental sensing technology;

c) means to protect the personal care robot from falling due to different elevations (e.g. stairways, holes), or from rolling over, shall be provided for the intended operational environments (see 6.5.2.2);

d) restriction of the dynamics (e.g. speed, acceleration and centre of mass) of the personal care robot within limits that ensure the robot will not overturn, even when attempting to turn on a worst-case travel surface gradient identified within the intended environment specified for the robot;

e) availability of seat belts in person carrier robots;

f) continuous sensing of passenger positioning for safe transport in person carrier robots and appropriate reaction (e.g. a protective stop) if incorrect position is detected;

g) use of warning signals, e.g. audio, visual, vibrations, or any combination of signals.

Any control systems performing the above functions shall conform to 6.1, in accordance with the personal care robot’s risk assessment.

5.10.3.4 Information for use

Information for use shall specify conditions of the environment under which the personal care robot can operate. For environmental conditions that might lead to hazardous situations but are likely to be found in situations where the robot performs its tasks, the information for use shall contain warnings.

For person carrier robots, information for use shall be provided to the user (passenger) with appropriate instruction and warnings to encourage the user to wear the protective means provided (i.e. seatbelt, helmet, etc.).

Proper training shall be provided to avoid abnormal and abrupt operations, e.g. sudden turns, accelerations/decelerations.

5.10.3.5 Verification and validation

Travel stability performance shall be evaluated under various safety-related surface conditions according to the results of risk assessment (surface conditions, e.g. carpets, metal tiles, plastic laminates and turfs).

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

5.10.4 Instability while carrying loads

5.10.4.1 General

Changes in the kinematic properties of the personal care robot due to the load (including passengers) shall not cause any hazard.

Any human near the personal care robot shall be protected from falling safety-related objects when the robot performs tasks, as well as while carrying up to maximum loads. This shall include uneven loads and movable loads (e.g. fluids sloshing in storage containers).

Risk assessment shall consider the consequences of dropped loads and any actions required by the personal care robot in the aftermath of any such event.

For emergency operation, the maximum deceleration rate shall be commensurate with emergency stop dynamic criteria including the requirements for load stability and retention.

5.10.4.2 Inherently safe design

The following measures shall be applied where appropriate:

a) the holders, placement areas, racks, etc., on the personal care robot, but especially end effectors (e.g. grippers or robotic hands), shall be designed to avoid the potential for accidents by lost loads;

b) use of form fitting designs;

c) use of passive means of securing loads (e.g. screws, elastic ties, spring-loaded clamp);

d) limiting devices to avoid handling of loads exceeding the maximum rated payload.

5.10.4.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) loads shall be tied or locked down by bolting or latching devices, or held by a gripping device;

b) the maximum speed and acceleration shall be commensurate with requirements for load stability during normal operation;

c) for normal operation, including a protective stop or an emergency stop, the deceleration rate shall be commensurate with requirements for load stability.

Any control systems performing the above functions shall conform to 6.1, in accordance with the personal care robot's risk assessment.

5.10.4.4 Information for use

Information for use shall contain information about maximum size and/or weight and type of loads (if appropriate), and their limits that may be carried. Where loads require fastening, instructions shall be provided.

5.10.4.5 Verification and validation

The performance of hands, grippers, and fittings shall be determined by a series of extreme movements, e.g. acceleration, stops, and U-turns of the mobile personal care robot and fast manipulator movements. All tests shall be carried out with maximum load and with the maximum speed.

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

5.10.5 Instability in case of collision

5.10.5.1 General

Safety-related objects shall be protected from hazardous movements after or during a collision. A collision between a personal care robot and any other safety-related obstacle should not cause instability of the robot.

a) Risk assessment shall determine the allowable maximum values of the appropriate parameters (e.g. contact force) that have an influence on the risk caused by contact over the entire operational range.

b) A personal care robot shall be designed to ensure that it does not cause any hazardous rollovers, runaways, or detachment of robot body parts, even when it receives any collision forces or safety-related obstacle detection signals during its motion, up to the limits specified for its intended operation.

5.10.5.2 Inherently safe design

The following measures shall be applied where appropriate:

a) design of the mass distribution and shape of the personal care robot so that unintended collisions within the maximum expected limits do not result in overturning;

b) use of soft materials to absorb forces which lead to hazardous instability.

5.10.5.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) use of airbags or seat belts to prevent harm, in case the personal care robot overturns;

b) design of braking performance of the mobile platform of the personal care robot to prevent runaway under a collision of the maximum expected force (see 6.2.3);

c) design of the motion behaviour of the personal care robot to minimize impact forces (see 6.6);

d) use of safety-related speed control (see 6.4) to minimize instability and high impact forces during collisions.

5.10.5.4 Information for use

The information for use shall contain details of all parameters that evaluate the extent of potentially hazardous forces and collision scenarios that can be tolerated.

5.10.5.5 Verification and validation

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

5.10.6 Instability while attaching or removing a restraint type physical assistant robot

5.10.6.1 General

Restraint-type personal care robots (e.g. exoskeletons) shall be designed in a way that stability is ensured while the robot is attached/removed to/from the user.

Robots that remain switched off during attaching/removing shall be designed in a way that they can be moved without effort in the required position and that unexpected start-up is prevented.

Robots that are moved with drive power during attaching/removing shall be designed in such a way that no hazardous movements can occur and forces on parts of the human body cannot cause any harm.

5.10.6.2 Inherently safe design

The following measures shall be applied where appropriate:

a) means to attach/remove the robot to the human shall be designed in a way that the human can stay in a stable position (e.g. sitting, lying) during the attaching/removing procedure;

b) use of actuators of sufficiently low power that the user cannot be harmed while attaching or removing the robot.

5.10.6.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate.

a) The robot shall be designed to detect that the robot is not properly attached to the user. If it is not attached properly, the robot shall provide a warning and come to a safe state.

b) During the attaching procedure, the force and velocity of the robot joints shall be restricted to safety-related speed control (see 6.4) and safety-related force control (see 6.7).

c) The robot shall be designed in a way that intended removal or unintended separation of the robot during normal operation leads to a safe state.

5.10.6.4 Information for use

Information for use shall contain instructions about attaching/removal of the robot to the user, including necessary configuration of the robot and appropriate environmental and terrain conditions.

5.10.6.5 Verification and validation

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

5.10.7 Instability during embarkation/disembarkation of a person carrier robot

5.10.7.1 General

Person carrier robots shall be designed to ensure that they do not roll over or run away while a passenger is getting on or getting off the robot under intended use situations.

5.10.7.2 Inherently safe design

The following measures shall be applied where appropriate:

a) design of the mass distribution and shape of the robot so that embarkation/disembarkation does not result in overturning;

b) design of the braking performance of the mobile platform of the person carrier robot to prevent runaway during passenger embarkation/disembarkation.

5.10.7.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) the person carrier robot shall be designed to include measures for active stability control that are capable of adjusting the balance of the robot to counteract any fluctuations to the centre of gravity during passenger embarkation/disembarkation according to 6.1;

b) the person carrier robot shall be in the appropriate configuration before starting embarkation/disembarkation under normal situations;

c) the person carrier robot shall be designed to be moved into a sufficiently safe configuration to allow disembarkation in emergency situations;

d) detect the presence of passenger in the correct position in or on the robot before start of travel can be enabled.

5.10.7.4 Information for use

Information for use shall contain instructions about embarkation/disembarkation procedures and precautions to be undertaken by the user. It shall also contain information about the necessary configuration of the robot for embarkation/disembarkation.

5.10.7.5 Verification and validation

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

5.10.8 Collision with safety-related obstacles

5.10.8.1 General

Personal care robots shall be designed such that the risk of hazardous collisions with safety-related obstacles (see 3.21.2) is as low as reasonably practicable (see 4.3, Note 2). A risk assessment shall be made including procedures of how to manage collisions between a personal care robot and safety-related obstacles.

5.10.8.2 Inherently safe design

This may include, but not be limited to, the following measures (see also 5.10.5):

a) physical limitation of the travel speed of the personal care robot to an inherently safe maximum;

b) moving parts shall be designed so that acceptable impact energy cannot be exceeded;

c) use of materials or structures to reduce impact forces to levels that do not cause harm.

5.10.8.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) calculating a minimum distance between the personal care robot and a safety-related obstacle, in accordance with ISO 13855, while the default human approach speed can vary depending on the application, and stop the robot if this distance is not maintained: this can be achieved by position and speed controlling (see 6.3) or by functions that avoid the safety-related obstacle, e.g. electro-sensitive protective equipment (ESPE)(see 6.5.2.1);

   NOTE 1 Annex B presents safety criteria for personal care robots.

   NOTE 2 Annex C presents an example application of a personal care mobile robot with an safety-related obstacle avoidance capability. The speed of the robot can be controlled in the safeguarded space, where the relative velocity of safety-related obstacles is detected and can be used for reduced speed control.

b) executing a protective stop (see 6.2.2.3), when a safety-related obstacle is in the personal care robot's protective stop space;

c) hand-guiding or steering the personal care robot. In this case, the risk assessment shall consider if all collisions with the robot can be avoided.

NOTE 3 Since applicable standards such as the ISO 13855 series are not intended for small children and infants, it is important that stronger or more demanding requirements for detection are considered (e.g. lower pressure for bumper actuation, smaller resolution of ESPE in order to detect the smaller limbs of children) when deemed necessary by risk assessment.

In order to reduce the effects of possible collisions, one or more of the following measures shall be applied:

— use of safety-related speed control (see 6.3);

— use of safety-related force control (6.7);

— use of safety-related contact sensing (6.5.2.2).

5.10.8.4 Information for use

Information for use shall describe the collision avoidance behaviour of the robot. Where any degree of manual control is required for collision avoidance, information for use shall provide the user instructions required and the limits of the applied control measures.

5.10.8.5 Verification and validation

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

5.10.9 Hazardous physical contact during human-robot interaction

5.10.9.1 General

When tactile interaction between a human and robot is intended during the use of a personal care robot, functions to guarantee human safety during the tactile interaction shall be identified by risk assessment (see 4.3, Note 2). The following aspects shall be taken in consideration:

a) detection of humans in the robot's maximum space;

b) during the intended tactile interaction, the physical reaction (e.g. contact force) from the robot to humans shall be designed to be as low as reasonably practicable;

c) the personal care robot shall be designed, as far as is reasonably practicable, to avoid unintended tactile interaction between human and other parts of the robot other than those intended for the interaction.

5.10.9.2 Inherently safe design

In all application tasks involving physical human-robot interaction, a personal care robot shall be designed to reduce, as far as is reasonably practicable, any levels of skin-robot friction, shear stresses, dynamic shocks, torques, arcs of centre of gravity, weight-bearing transfers and supports of the human body.

5.10.9.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) software-controlled limits to the personal care robot workspace (see 6.3);

b) speed restriction and safety-related speed control (see 6.4);

c) force restriction and safety-related force control as (see 6.7).

5.10.9.4 Information for use

Information for use shall provide information about intended tasks and situations for human-robot interaction, including possible limitations with respect to user groups, environmental conditions, etc.

Instructions shall be provided as to how users should operate the personal care robot in order to avoid injury, and warnings shall be provided about the potential injuries that might be sustained if the instructions are not obeyed.

5.10.9.5 Verification and validation

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

5.11 Hazards due to insufficient durability

5.11.1 General

A personal care robot shall be designed and built in such a way that its durability is ensured throughout its design life without creating a hazard.

The minimum durability requirements of the personal care robot shall be determined by its risk assessment. The following shall be taken into consideration:

— mechanical stresses;

— materials and their properties;

— vibration and other emissions;

— environmental conditions (e.g. thermal, moisture);

— maximum operational conditions derived from operation under extreme situations (like unexpected turns, accelerations decelerations, and adverse environmental conditions) including foreseeable misuse scenarios and situations.

5.11.2 Inherently safe design

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

a) mechanical failure shall be prevented by adherence to appropriate standards, e.g. ISO 13823;

b) overload prevention measures should be incorporated into a personal care robot's design, including those mechanisms described in ISO 12100 (if used, the mechanisms shall conform to appropriate established standards);

c) appropriate fatigue limits shall be applied to the personal care robot's components that are subject to variable stresses;

d) appropriate static and dynamic balancing of rotating components;

e) the design of electrical devices, especially electrical harnesses and connectors shall take into account the expected number of use cycles;

f) inclusion of passive heat dissipation (e.g. by conduction or convection).

5.11.3 Safeguarding and complementary protective measures

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

a) control functions to monitor/regulate the applied forces as mentioned in 6.7;

b) use of active heat dissipation methods (e.g. with fans or other cooling systems);

c) where necessary, temperatures inside the personal care robot, especially near heat sources shall be monitored: the robot shall react in an appropriate way (e.g. shutting itself off in a safe manner), if temperature limits are exceeded;

d) monitoring the life cycle of the personal care robot and inform the user when maintenance time or end of life is reached.

5.11.4 Information for use

Information for use shall specify maintenance procedures necessary for ensuring the durability of the personal care robot such as the regular exchange of parts.

If replacement of the electrical connection harness is required in order to protect the personal care robot from unwanted electrical noise caused by the harness, the use limit of the electrical connection harness shall be depicted in the information for use, based on the frequency of the connection/disconnection of the harness.

If electrical power is supplied directly (with electrical cables), the use limit of the electrical connector shall be depicted in the information for use, based on its frequency of connection/disconnection.

5.11.5 Verification and validation

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

5.12 Hazards due to incorrect autonomous decisions and actions

5.12.1 General

A personal care robot that is designed to make autonomous decisions and actions shall be designed to ensure that wrong decisions and incorrect actions do not cause an unacceptable risk of harm.

EXAMPLE 1 A mobile servant robot grasping the wrong drink and serving coffee instead of water in a cup might be an acceptable risk, whereas serving a drink in a broken glass might be an unacceptable risk.

EXAMPLE 2 While a person carrier robot making an abrupt and unexpected evasion movement in an area with smooth ground might be an acceptable risk, making an evasion movement in an area with slippery ground might be an unacceptable risk.

The risk of harm occurring as an effect of incorrect decisions can be lowered either by increasing the reliability of the decision (e.g. by better sensors) or by limiting the effect of a wrong decision (e.g. by narrowing the limits of use).

5.12.2 Inherently safe design

The following measures shall be applied where appropriate:

a) constraining the operational scenarios to reduce risk of harm due to incorrect actions;

b) use of unique identifiers for safety-related objects, travel paths, etc.

5.12.3 Safeguards and complementary protective measures

The following measures shall be applied where appropriate.

a) The capability/reliability of sensors and sensing algorithms shall be increased to a level where no unacceptable risk occurs.

b) Identification algorithms shall be designed in a way that the probability of a certain decision being correct (e.g. probability of having identified a certain safety-related object correctly) is calculated and can be monitored. Decisions with a high uncertainty outcome shall be re-evaluated using alternative approaches and/or additional information. If, after the re-evaluation the uncertainty remains unacceptable, external assistance shall be sought or a protective stop shall be initiated.

c) Validity checks shall be made on decisions which can lead to hazardous situations.

   EXAMPLE The correct identification of a safety-related object can be checked by taking into account the place where it is found or the time and place where this object was seen the last time.

d) Decisions shall be verified by diverse sensing principles.

All personal care robot functions implementing requirements a) to d) shall conform to control system performance requirements described in 6.1, in accordance with the robot's risk assessment.

5.12.4 Information for use

The limits of use shall exclude situations in which decisions cause an unacceptable risk of any harm, taking into account foreseeable misuse.

The information for use shall inform about the sensing and decision making capabilities of the personal care robot, and shall give instructions on how to prevent harm due to wrong actions and decisions.

5.12.5 Verification and validation

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

5.13 Hazards due to contact with moving components

5.13.1 General

Personal care robots shall be designed so that the risk of hazards caused by exposure to components such as motor shafts, gears, drive belts, wheels, tracks or linkages is acceptable.

Personal care robots shall be designed in compliance with ISO 13857 in order to prevent hazard zones being reached by parts of the body.

5.13.2 Inherently safe design

The following measures shall be applied where appropriate:

a) the personal care robot shall be designed with the minimum number of accessible moving parts;

b) the personal care robot shall be designed with moving parts in which components such as motor shafts, gears, drive belts, wheels, tracks or linkages are not exposed.

5.13.3 Safeguards and complementary protective measures

Hazards due to moving parts shall be prevented either by fixed guards or by movable guards, depending on the foreseeable frequency of access, in accordance with ISO 14120.

Appropriate method(s) shall be chosen from the following.

a) Where fixed guards are used, the following measures shall apply:

   1) fixed guards shall be installed so that they can be opened or removed only with tools;

   2) their fixing system shall remain attached to the guards or to the personal care robot when the guards are removed, if deemed necessary by risk assessment;

   3) where possible, guards shall be incapable of remaining in place without their fixings.

b) Where movable guards are used, the following measures shall apply:

   1) movable guards shall be designed so that they cannot be removed easily, and once opened, remain attached to the personal care robot;

   2) movable guards shall be interlocked with the hazardous movements in such a way that hazardous movements come to a stop; the control system performing this function shall conform to Clause 6 in accordance with the personal care robot's risk assessment; the guard shall remain closed and locked until the risk due to the hazardous machine functions covered by the guard has disappeared, in accordance with ISO 14119;

c) Enclosures shall be used to provide protection against rotating components.

5.13.4 Information for use

Where fixed or movable guards are incorporated into a personal care robot design, information for use shall include all instructions necessary for their correct installation, adjustment and removal.

5.13.5 Verification and validation

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

5.14 Hazards due to lack of awareness of robots by humans

5.14.1 General

Where risk assessment shows that lack of awareness of robots by humans is a hazard, e.g. where silent operation can increase the probability of collision with persons, the personal care robot shall emit noticeable sound to reduce risk without violating other noise emission restrictions.

Where warnings or alarms are used, risk assessment shall be used to balance the risk of hazards due to silent operation against hazards due to high levels of noise or unexpected noise.

NOTE 1 Warnings (e.g. acoustical, visual) might annoy the user or any human near the personal care robot, causing them to manipulate the robot in order to cease the signal.

NOTE 2 Alternative indications might also be required for users with disabilities, e.g. those who have visual impairment or difficulty with hearing.

5.14.2 Inherently safe design

Where needed, the personal care robot shall be designed in a way that it has a highly-noticeable appearance, and produces noticeable sound without reaching harmful noise levels.

5.14.3 Safeguards and complementary protective measures

The following measures shall apply where appropriate:

a) acoustic emitters shall be provided to warn users of potential hazardous situations;

b) warning lights or other optical devices shall be provided to alert users and third parties to the presence of the personal care robot;

c) the personal care robot shall stop while a safety-related object is in its protective stop space, and shall continue to perform its tasks when it has left.

5.14.4 Information for use

Where the manufacturer has identified a particular hazard relating to lack of awareness, warnings and advice to users shall be provided in the information for use.

5.14.5 Verification and validation

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

5.15 Hazardous environmental conditions

5.15.1 General

Personal care robots shall be designed in such a way that foreseeable environmental conditions during the intended use do not lead to hazards.

Personal care robots shall be protected from causing hazards due to the presence or build-up of sand or dust in the environment. Where there is a risk of any hazard caused by dust contamination of the robot (as determined by risk assessment) then all affected parts, components or subsystems of the robot shall be designed to achieve a minimum protection rating of IP 6X, as defined in IEC 60529. Where dust ingress is not a concern, and sand ingress is the only hazard risk (as determined by risk assessment) then all affected parts, components or subsystems of the robot shall be designed to achieve a minimum protection rating of IP 5X, as defined in IEC 60529.

Personal care robots shall be designed to prevent dust-related fires due to high temperature components (see 5.7.4). The robots shall be designed to prevent hazardous electrostatic charge build-up (see 5.5), to prevent dust building up on charged outer surfaces.

Personal care robots shall be designed so that water and moisture ingress does not cause any risk. Where there is a risk of any hazard caused by water or moisture in the robot (as determined by risk assessment) all parts, components, subsystems and internal enclosures of personal care robots shall be designed to achieve a minimum protection rating of IP X6 (resistant to pressurized water sprays for three minutes), as defined in IEC 60529.

If a personal care robot is intended to operate in cold external environments, then it shall be designed to be tolerant of snow and ice conditions. Moving parts and electrical components shall be prevented from failure due to ice build-up. Moving parts shall be designed to be tolerant of water, moisture, dust, and sand. Electrical components shall either be sealed against water or moisture, or installed inside enclosures that provide this protection. Electrical power supplies and batteries shall be protected against short circuits caused by immersion in water or build-up of moisture.

If a given personal care robot might foreseeably operate in coastal areas, in other locations near oceans, seas, other salt water bodies, or in shipboard environments, then its risk assessment shall consider the effects of high salinity atmospheres and salt-water sprays. If salt corrosion is assessed to be potentially hazardous, robots shall be provided with sufficient protection to ensure an acceptable level of risk.

5.15.2 Inherently safe design

The following measures shall be applied where appropriate:

a) sealing of joints and other moving parts;

b) dust-resistant materials for moving parts;

c) coating or sealing of electrical components;

d) selection of materials and adoption of measures for inherent protection against extreme temperatures (see 5.7.4.2);

e) water- or moisture-resistant materials;

f) saline-resistant material or coatings, e.g. paints, varnishes or organic coatings.

5.15.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) mechanisms to prevent dust build up (e.g. forced ventilation or washing mechanisms);

b) dust detection and warning indications to instruct the user to perform the necessary actions;

c) air filters at the enclosure openings;

d) use of heating to melt snow or ice, or evaporate moisture or small water droplets, so as to dry out the personal care robot without subsequent hazards;

NOTE 1 Melting snow and ice might lead to water/moisture hazards, if not designed correctly.

e) removing water/moisture from surfaces (e.g. using wipers);

f) external removal of snow or ice from surfaces (e.g. by washing with hot water);

g) active detection of snow/ice/cold air conditions, and execution of a protective stop before snow/ice levels build up to unacceptable levels; the robot shall make an appropriate indication to the user as to the reason for the stop;

h) the personal care robot shall incorporate a safeguard function that ensures the periodic stopping or shutdown for maintenance (which will typically include inspection and either cleaning or parts replacement); the robot shall provide indication to the user that it is shutting down for this purpose: for the purposes of this requirement, the period between shutdowns shall be based on the time required for unacceptable risk levels being reached due to, for example, corrosion, build up of sand, dust or snow.

NOTE 2 ISO 4629 provides guidance on the assessment of degradation of paints and varnishes.

5.15.4 Information for use

Where any action by the user is required for the prevention of risks, all necessary actions as well as appropriate materials (e.g. tools, cloths, fluids) shall be provided in the information for use. This may include:

— inspection, e.g. with respect to salt corrosion or sand abrasion;

— cleaning for the prevention or removal of sand, dust, snow and ice;

— drying;

— maintenance and replacement of parts.

5.15.5 Verification and validation

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

The IP rating of the personal care robot shall be validated in accordance with IEC 60529.

Where salt spray tests are necessary, they shall conform to ISO 9227. Where corrosion of optical sensor surfaces is significant, they shall be tested in accordance with ISO 21227-3.

5.16 Hazards due to localization and navigation errors

5.16.1 General

A personal care robot capable of localization and navigation shall be designed in a way that uncertainty in localization and navigation errors does not lead to an unacceptable risk.

Uncertainty in localization shall not lead to hazardous movement of the mobile platform or any other part of the robot. Localization errors which can cause the robot to enter a forbidden area or to lose mechanical stability in a hazardous manner (e.g. by falling downstairs) shall be prevented.

The navigation capability of a personal care robot shall be sufficient so that motion planning to any reachable goal can be realized, and that the generated path avoids the positions of any pre-known safety-related obstacles without causing any unacceptable risk of collision and mechanical instability.

If localization and navigation are used for risk reduction, these control system functions shall conform to the requirements of 6.1.

5.16.2 Inherently safe design

The following measures shall be applied where appropriate:

a) designing the personal care robot for environments and tasks where navigation capability is not needed to reduce risks;

b) implementation of safety functions for collision avoidance, travel surface sensing, etc., in a way that navigation capability is not required for safe operation of the personal care robot;

c) where landmarks (natural or artificial) are used for localization, a sufficient number of landmarks shall be detectable for the personal care robot from any point of its restricted space: the landmarks or markers used for navigation shall be unambiguous.

5.16.3 Safeguarding and complementary protective measures

The following measures shall be applied where appropriate:

a) monitoring the stability and confidence of localization and entering a safe state in case of unstable localization;

b) compensation of unstable localization, e.g. by use of odometry or other sensor data;

c) navigation maps shall be updated with new information (e.g. from internal sensors or external sources) with a sufficiently high frequency determined by risk assessment, to prevent risks originating from the use of an outdated map.

5.16.4 Information for use

Information for use shall specify the intended environment for operation, and shall provide information under which conditions localization errors or navigation errors can occur.

5.16.5 Verification and validation

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

6 Safety-related control system requirements

6.1 Required safety performance

6.1.1 General

Where protective measures are implemented through a control system, the requirements of Clause 6 shall apply. The required performance level (PL) or safety integrity level (SIL) of the control system functions (electric, hydraulic, pneumatic, and software) of a personal care robot shall be determined by risk assessment, and shall conform to either ISO 13849-1 or IEC 62061. This shall include verification and validation.

If one or more of the following functions are used for risk reduction, a PL or a SIL shall be defined for each of the used functions unless 6.1.4 applies:

a) emergency stop (6.2.2.2);

b) protective stop (6.2.2.3);

c) limits to workspace 6.3 (including forbidden area avoidance 6.5.3);

d) safety-related speed control (6.4);

e) safety-related force control (6.7);

f) hazardous collision avoidance (6.5.2.1, 6.5.2.2);

g) stability control (including overload protection) (6.6, 6.7).

In the following subclauses, two sub-types of each type of personal care robot are defined, representing two levels of risk. It is up to the manufacturer to decide which category or categories apply.

6.1.2 Personal care robot types

6.1.2.1 Mobile servant robot

— Type 1.1: small AND light weight AND slow AND no manipulator.

— Type 1.2: large OR not light weight OR fast OR with manipulator.

6.1.2.2 Physical assistant robot

6.1.2.2.1 Restraint type

— Type 2.1: Low powered physical assistance (user can overpower personal care robot).

— Type 2.2: High powered physical assistance (user cannot overpower personal care robot).

6.1.2.2.2 Restraint-free type

— Type 2.3: low powered AND no autonomous mode AND statically stable AND lightweight AND slow.

— Type 2.4: not low powered OR autonomous mode OR not statically stable OR not lightweight OR fast.

6.1.2.3 Person carrier robot

— Type 3.1: standing, single passenger AND indoor flat surfaces AND slow AND lightweight AND semi-autonomous.

— Type 3.2: multiple passengers OR non-standing passengers OR outdoor OR uneven surfaces OR not slow OR not lightweight OR autonomous.

NOTE 1 A size is considered to be "small" if it is sufficiently low that a falling or overturning robot cannot collide with the upper body of a user (including a sitting or lying person, depending on the intended use). A maximum size which can be considered as small is determined by the manufacturer considering intended task and user groups.

NOTE 2 A weight is considered to be "lightweight" if it is sufficiently low that injuries other than minor injuries due to impact are unlikely and that a single user can lift the weight to free oneself if being trapped. A maximum weight which can be considered as lightweight is determined by the manufacturer considering intended tasks and user groups.

NOTE 3 A speed is considered to be "slow" if it is below the normal walking speed of the intended user group as determined by risk assessment. For a healthy adult, walking speed is usually assumed to be up to 6 km/hr.

NOTE 4 A power is considered to be "low powered" if it is sufficiently low that injuries other than minor injuries are unlikely after inherently safe design measures have been applied. A maximum power which can be considered as low powered is determined by the manufacturer considering intended tasks and user groups.

NOTE 5 "Statically stable" assumes that the stability of the robot is maintained during stand-still without drive power after inherently safe design measures have been applied. Depending on the intended use of the robot, this includes maintaining stability of both the user and the robot when the user is in contact with the robot, e.g. by gripping handles attached to the robot or leaning on the robot.

6.1.3 Required performance level for selected personal care robot types

The performance levels specified in Table 1 define standard performances that are expected to provide sufficient risk reduction in most applications. However, it does not follow that in all applications safety functions with these PLs will provide all the required risk reduction. The performance levels specified in Table 1 shall be met unless 6.1.4 leads to a different requirement.

Table 1 — Performance levels for personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
6.2.2.2 Emergency stop	d (no low risk option)		c	d	c	d	d	d
6.2.2.3 Protective stop	b	d	b	d	b	c	c	e
6.3 Limits to workspace (incl. forbidden area avoidance 6.5.3)	b[1]	d	b	d	a	d	N/A	e
6.4 Safety-related speed control	b	d	b	b	b	d	c	e
6.7 Safety-related force control	b	d	b[3]	e[4]	a	b[5]	N/A	N/A
6.5.2.1, 6.5.2.2 Hazardous collision avoidance	b	d	N/A	N/A	b	d	N/A	e[6]
6.6, 6.7 Stability control (incl. overload protection)	b	d[2]	N/A	c	b	d[2]	b[7]	d[2]

[1] Avoiding forbidden areas shall have PL d.

[2] If the personal care robot is inherently unstable, PL e is required.

[3] If the risk assessment shows that the user might not be able to overpower the personal care robot due to any particular situation (e.g. being unconscious), the Type 2.2 requirement shall apply unless the robot has an inherent limitation that prevents harm being caused.

[4] If other limiting functions (e.g. workspace or speed limitation) also provide protection against the same risk, PL d is allowed, provided that all the relevant functions are designed to this level.

[5] If force control is used for collision avoidance or actively holding the person, PL d is required.

[6] The control system shall achieve PL e, but this might not be achievable for sensing mechanisms. In this case, the risks caused by systematic failure of sensors shall be reduced as low as reasonably practicable.

[7] If the personal care robot is inherently unstable, PL c is required.

6.1.4 Application specific performance level requirements

The results of a comprehensive risk assessment performed on the personal care robot and its intended application may determine that safety-related control system performance levels higher or lower than those stated above are necessary for the application, and shall be met.

Selection of one of these higher or lower safety-related performance levels shall be specifically identified, and appropriate limitations and cautions shall be included in the information for use provided with the affected equipment.

6.1.5 Alternative methods

Other standards offering alternative performance requirements (e.g. control reliability) may also be used (e.g. ANSI/RIA R15.06-1999, 4.5.4). When using these alternative standards to design safety-related control systems an equivalent level of risk reduction shall be achieved.

6.2 Robot stopping

6.2.1 General

The personal care robot shall be designed to ensure that it comes to a safe stop without causing any hazardous rollovers, runaways, or drops of robot parts and loads if there is intentional braking at any speed.

The halt states can vary depending on a personal care robot type, and thus the halt states of a robot shall be defined by the robot manufacturer. If the halt state is achieved and maintained by the robot's normal speed control function, the function shall conform to 6.6. When the halt state is achieved by an independent stopping function, it shall be achieved only by a braking mechanism, to which the following requirements shall be applied:

a) it shall operate on interruption of the power supply, where applicable;

b) it shall stop the personal care robot within the operating range of the supplied safety-related object detection device(s), taking into account the specified limits on all parameters, e.g. load, speed, travel surface coefficient of friction and gradient and expected wear condition of the robot's parts;

c) it shall maintain the personal care robot, and its maximum allowable load stationary on the maximum operational travel surface gradient specified by the manufacturer;

d) it shall operate on loss of critical control functions.

6.2.2 Robot stopping functions

6.2.2.1 General

The personal care robot shall have a protective stop function, and an independent emergency stop function shall be provided as required by the risk assessment. Optionally these functions can have provision for the connection of external protective devices, and an emergency stop output signal may be provided. Table 2 provides a comparison between emergency stop and protective stop functions.

NOTE In some applications, a protective stop includes providing driving power to maintain system stability. An example of this could be a walking personal assistant robot.

Table 2 — Comparison of emergency and protective stops

Function	Emergency stop	Protective stop
Purpose	Emergency	Safeguarding or risk reduction
Stop category (IEC 60204-1)	0 or 1	0, 1 or 2
Initiation	Manual	Manual, automatic or may be automatically initiated by a safety-related function
Safety-related system performance	Shall meet performance in 6.1	Shall meet performance in 6.1
Reset	Manual only	Manual or automatic
Use frequency	Infrequent	Often to infrequent
Effect	Remove power from the actuators to stop propagating the hazardous situation	Safely control the safeguarded hazard

6.2.2.2 Emergency stop

If an emergency stop capability is required, each command device capable of initiating robot motion or other hazardous situation shall have a manually initiated emergency stop function that:

a) conforms to requirements of 6.1 and IEC 60204-1, and takes precedence over all other robot controls;

b) causes all controllable hazards to stop;

c) removes drive power from the robot actuators if the robot is in a safe state;

d) provides capability for controlling hazards controlled by the robot system;

e) remains active until it is reset;

f) shall only be reset by manual action that does not cause a restart after resetting, but shall only permit a restart to occur.

If the provision of an emergency stop button on a command device is not possible (e.g. for speech interfaces, computer screen-based or remote applications) it shall be ensured that an equal level of safety is reached with the existing emergency stop facilities (e.g. button(s) directly on/near the personal care robot).

Selection of a category 0 or category 1 stop for the function shall be determined from the risk assessment, according to IEC 60204-1.

The emergency stop device shall be in accordance with IEC 60204-1 and ISO 13850.

The emergency stop performance shall conform to 6.1. The different kinds of personal care robots shall meet the PLs in Table 3.

Table 3 — Performance levels for emergency stop of personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
Emergency stop	d (no low risk option)		c	d	c	d	d	d

6.2.2.3 Protective stop

When risks are mitigated by the use of safety-related control functions, the personal care robot shall have one or more protective stop functions. The categories of these stop functions (as described in IEC 60204-1) shall be determined by risk assessment for the application.

These stop functions should control the safeguarded hazards by causing a stop of all hazardous robot motion, removing or controlling power to the robot drive actuators, and allowing for the control of any other hazard controlled by the robot system. The stop may be initiated manually or by control logic. The restart shall be initiated manually unless risk analysis allows automatic restart.

The protective stop function performance shall conform to the requirements of 6.1.

The personal care robot may have a protective stop function using stop category 2, as described in IEC 60204-1, that does not result in drive power being removed but does require monitoring of the stand-still condition after the robot stops. Any unintended motion of the robot in the stand-still condition, or failure of the protective stop function should result in a category 0 stop, according to IEC 60204-1, as determined by risk assessment. The stand-still and monitoring function performance shall conform to 6.1. See Table 4.

NOTE This can include a monitored category 2 stop function, according to IEC 60204-1, provided by an electric power drive system, which corresponds to a safe operational stop according to IEC 61800-5-2.

Table 4 — Performance levels for protective stop of personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
Protective stop	b	d	b	d	b	c	c	e

6.2.3 Braking performance

The design of the control systems functions that issue a protective stop of the robot's mobile platform shall consider the braking performance of the platform, and thus the distance the personal care robot needs to stop, under all foreseeable travel surface conditions.

Braking performance shall be sufficient so that a hazardous collision with any safety-related obstacle can be avoided when the personal care robot is travelling at its rated speed and rated load under specified travel surface conditions. As far as reasonably practicable the robot shall also be able to stop in front of a safety-related object under the worst expected travel surface conditions as determined by risk assessment.

One of the following applies.

a) If control system functions are used to evaluate the braking performance of a personal care robot and/or to set a safety-related speed limit for a particular travel surface, they shall comply with 6.1, considering all intended operating conditions.

b) The personal care robot shall be able to estimate surface conditions in advance and avoid dangerous surface conditions if reasonably practicable. This function shall comply with 6.1, considering all intended operating conditions.

6.3 Limits to operational spaces

Figure 1 illustrates operational spaces for personal care robots.

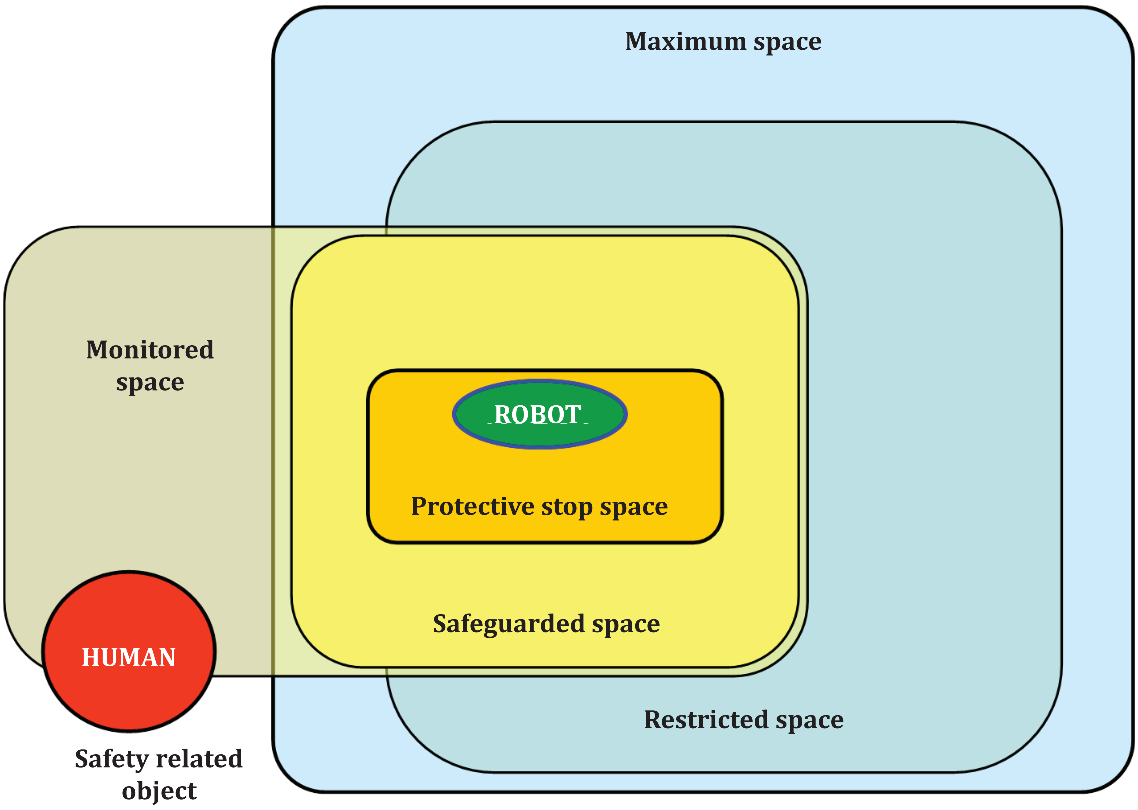


Figure 1 — Operational spaces for personal care robots

Operational space limitation might be required for risk reduction, for either constraining the personal care robot motion within a defined volume or for preventing the robot from entering it (inclusion and exclusion zones using the operational spaces, see Annex B).

Software limits are permitted as a means to define and reduce the restricted space, provided they can affect a stop of the robot at full rated load and speed. The restricted space shall be bounded by the actual expected stopping position that accounts for the stopping distance travelled. The manufacturer shall state the capability in the information for use, and shall disable the software limits if this capability is not supported.

Control programs that monitor and perform joint and space limiting functions based on software limits shall conform to 6.1, and be changeable only by authorized personnel. If the software limit is violated, a safe state shall be initiated. Motion during a limit violation shall be under safety-related speed control, as described in 6.4. Active settings and configuration of the safety limits shall be recorded so that changes to the configuration can be easily identified and reviewed. See Table 5.

Table 5 — Performance levels for limits to workspace control function of personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
Limits to workspace (incl. forbidden area avoidance)	b[1]	d	b	d	a	d	N/A	e
1 Avoiding forbidden areas shall have PL d.								

6.4 Safety-related speed control

Risk assessment shall determine the safety-related speed limit of the personal care robot, beyond which the robot might cause harm. This shall be done by calculating speeds of representative points on the robot's accessible moving parts. Only authorized persons shall be able to adjust allowable maximum speed.

Depending on the task(s) executed by the personal care robot, different speed limits can exist, of which one is active in a given situation. An appropriate way for switching speed limits shall be determined by risk assessment.

The speed of the personal care robot shall be controlled to ensure that the speeds of the moving parts do not exceed safety-related speed limit.

When provided, safety-related speed control shall be designed and constructed so that in the event of a fault, the speed of the manipulator's end-effector and other robot parts shall not exceed the safety-related speed limits, and a safe state shall be issued when a fault occurs. The performance of the safety-related speed control shall conform to 6.1. See Table 6.

Table 6 — Performance levels for safety-related speed control of personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
Safety-related speed control	b	d	b	b	b	d	c	e

6.5 Safety-related environmental sensing

6.5.1 General

Safety-related environmental sensing shall conform to the requirements of 6.1. The objectives of the safety-related environmental sensing are the following.

a) Safety-related object sensing: this function shall be applied to avoid hazardous collisions. The safety-related objects to be detected might include humans, domestic animals, and other objects in the environment that are safety-related (see Note in 3.21.1). Object detection devices shall be applied to ensure admissible distances or contact forces between a safety-related obstacle and a personal care robot.

b) Travel surface sensing: this function includes the sensing of travel surface properties (e.g. smoothness, roughness and solidity) and travel surface geometry (e.g. flatness, slope, stairs and gaps), and shall be applied to avoid hazards related to instability.

6.5.2 Object sensing

6.5.2.1 Non-contact sensing

Non-contact sensing devices are used to:

— ensure minimum operational distances, and/or

— reduce the relative approach speed.

In order to avoid hazardous collisions and maintain the required level of safety, the following requirements apply.

a) When it is required to detect persons, electro-sensitive protective equipment (ESPE) according to the relevant parts of IEC 61496 shall be used.

b) If ESPE is used as the primary sensing device, it shall have an appropriate reliability in its operation and mounting shall be in accordance with the personal care robot's risk estimation.

c) When it is required to detect safety-related objects other than persons, other non-contact sensing equipment then ESPE can be applied and the detection capability and reliability of such equipment shall conform to requirements determined by risk assessment.

NOTE 1 IEC/TS 62046 gives guidance on the application of protective equipment.

Detection of one or more safety-related objects within a minimum distance shall cause the personal care robot to come to a safe state either by:

— initiating a protective stop according to 6.2.2.3, or

— initiating a safe speed reduction by the means of a safety-related speed control according to 6.4, or

— maintaining a separation distance to safety-related object(s).

Where the detection of persons is required, the minimum distance shall be determined according ISO 13855.

Where the detection of other safety-related objects than humans (domestic animals, walls, furniture, maximum space boundaries) is required, the separating distance shall be determined according the formulae of ISO 13855 but excluding the intrusion distance parameter "C".

If the non-contact sensing device provides reliable information about the relative approach speed of persons and allows the personal care robot to determine the worst-case relative speed between the robot and an approaching safety-related object, the calculation of the minimum distance can use the determined speed in replacement of K in the formulae of ISO 13855. The performance level of the non-contact sensing device shall not degrade the performance level of the required safety function. See Table 7.

NOTE 2 Annex C describes a typical example of how to calculate the relative speed from a personal care robot and a safety-related object moving in a different direction but might collide in the next movement phase.

Table 7 — Performance levels for hazardous collision avoidance control of personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
Hazardous collision avoidance	b	d	N/A	N/A	b	d	N/A	e[1]

1 The control system shall achieve PL e, but this might not be achievable for sensing mechanisms. In this case, the risks caused by systematic failure of sensors shall be reduced as low as reasonably practicable.

6.5.2.2 Contact sensing

Contact sensing is required for many human-robot interaction tasks. For this, the robot has to safely detect even small contact forces and react to them in an appropriate manner. Where necessary, contact detection has to ensure following capabilities:

a) contact shall be detected along the entire robot structure (i.e. on joint level);

b) the contact forces shall be limited to appropriate values as determined by risk assessment. it is advisable to obtain these limits by relying on the limits stated in other technical standards and scientific publications (see Bibliography).

Contact sensing used to detect persons shall conform to the requirements of the relevant parts of ISO 13856. If safety-related objects other than persons shall be detected, the required detection capability and reliability shall be determined by risk assessment.

Pressure-sensitive protective equipment (PSPE) (e.g. pressure-sensitive edges, bars, devices, bumpers, plates, wires) shall be used to prevent hazardous impacts. These contact sensing devices shall conform to this subclause, in accordance with the personal care robot's application and risk estimation. If used as a safety-related sensing device, the elements shall conform to 6.1, and shall be mounted as described in ISO 13856.

6.5.3 Travel surface sensing

Where there is an unacceptable risk of mechanical instability due to the conditions or the geometry of the travel surface, a personal care robot capable of autonomous travel shall be provided with the capability to sense or detect safety-related surface geometry and conditions, e.g. uneven terrain, stairs.

The means (on-board or off-board) of detecting the surface geometry and travel conditions shall be able to detect and judge whether the robot is capable of travelling through the monitored areas.

Surface condition detection performance shall be sufficient to allow the personal care robot to evaluate its braking performance in accordance with the requirements in 6.2.3 as well as to maintain its mechanical stability.

Where the environment of a personal care robot is equipped with markers, tags, and/or magnetic tapes that can be securely detected by a robot, they shall be placed in sufficient quantity and locations that the robot shall have no blind spots.

NOTE In order to validate the travel surface sensing function, it is advisable that various types of surface safety-related obstacles (i.e. gaps, bumps, and/or steps) be placed between the personal care robot and its travel destination. The robot performance can then be checked as to whether it can safely avoid the adverse surface conditions or safely stop without getting stuck.

6.6 Stability control

A personal care robot shall be stable in all intended and reasonably foreseeable use situations. The functional safety performance of the functions which provide stability shall conform to 6.1. The different kinds of personal care robots shall meet the PLs in Table 8.

Table 8 — Performance levels for stability control of personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
Stability control (incl. overload protection)	b	d[1]	N/A	c	b	d[1]	b[2]	d[1]

1 If the personal care robot is inherently unstable, PL e is required.

2 If the personal care robot is inherently unstable, PL c is required.

6.7 Safety-related force control

The force exerted on a human, or other safety-related objects, by any part of the personal care robot shall be controlled within the maximum safe contact criteria such as force limits.

Quantitative requirements on the maximum safe contact force/torque should be well-examined by ergonomic experimentation. The limits of the exerted force during unintended contact with a safety-related object may differ with application, and shall be determined by risk assessment.

Safety-related force control shall be achieved by a safety-related contact sensing and reaction scheme that brings the personal care robot to a safe state such that this force threshold cannot be exceeded.

The reaction to an unintended contact shall meet at least the following requirements:

a) reacting fast enough for contact forces to remain below safety-related force limits;

b) bringing the personal care robot into a safe state after the contacting incident.

NOTE For literature presenting approaches to determine allowed contact forces and pain tolerances, see Bibliography.

The functional safety performance of safety-related force controllers shall conform to 6.1. See Table 9.

Table 9 — Performance levels for safety-related force control of personal care robots

Safety functions of personal care robots	Type of robot							
	Mobile servant robot		Physical assistant robot				Person carrier robot	
	Type 1.1	Type 1.2	Type 2.1	Type 2.2	Type 2.3	Type 2.4	Type 3.1	Type 3.2
Safety-related force control	b	d	b[1]	e[2]	a	b[3]	N/A	N/A

1 If the risk assessment shows that the user might not be able to overpower the personal care robot due to any particular situation (e.g. being unconscious), the Type 2.2 requirement shall apply unless the robot has an inherent limitation that prevents harm being caused.

2 If other limiting functions (e.g. workspace or speed limitation) also provide protection against the same risk, PL d is allowed, provided that all the relevant functions are designed to this level.

3 If force control is used for collision avoidance or actively holding the person, PL d is required.

6.8 Singularity protection

Motions that pass near singularities can produce high axis speeds. These high speeds can be unexpected and induce risks to user, to the operator, and to people in the environment.

For personal care robot motions passing near singularities, one or more of the following measures shall apply:

a) control the motion through the singularity to avoid any hazard;

b) the robot shall avoid the singularity e.g. by performing an adjustment to the path planning;

c) stop the robot motion and provide a warning prior to the robot passing through a singularity or performing an evasion movement during the coordinated motion.

6.9 Design of user interface

6.9.1 General

When command devices (e.g. joysticks, operator control panels, voice and gesture recognition systems, and/or other means) are used to control the personal care robot's functions, they shall have an appropriate reliability in their operation.

Whether the command device is tethered or untethered to the personal care robot, its electrical connection to the robot shall not cause hazards.

Command devices shall provide control of individual or combined robot functions during manual and semi-autonomous robot control modes.

6.9.2 Status indication

The status of the command devices shall be clearly indicated at all times, e.g. power on, operational mode, fault detected. The status should be indicated in a conspicuous location for the operator.

In the case of remote controls, each command device shall clearly identify the parts of the personal care robot to be controlled from that unit. The remote control system shall be designed and constructed in such a way as to affect only:

— the related parts of the robot;

— the related functions.

6.9.3 Connection and disconnection

On connection, disconnection or reconnection of any command device, whether it is intentional or not, or if connection problems of the command device occur, the personal care robot shall perform a protective stop if continuing the task can lead to an unacceptable risk.

A remote controlled personal care robot shall be designed and constructed in such a way that it responds only to signals from the intended control unit(s).

6.9.4 Single command device for multiple robots

The control and switching of control for multiple personal care robots with one command device shall not cause any harm to the user or any exposed person. The command device may control one or more robots independently or at the same time.

It shall be clearly visible to the operator which personal care robot is under the control of the command device. Every robot to be controlled shall be selected before a command can be sent to it. An unexpected start up of any unselected robot shall be prevented.

6.9.5 Multiple command devices

If multiple command devices are used, the following shall apply:

a) a clear indication shall be provided for identifying each active command device;

b) each function of the personal care robot shall be controlled by only one command device at any time, except for the protective stop and emergency stop functions: in the case of a multimodal single user interface (e.g. simultaneous speech and gesture recognition), the multimodal communication interface may be considered as one command device;

c) measures shall be applied to prevent hazards derived from conflicting multiple commands;

d) changing the control from one command device to another shall not cause unacceptable risk;

e) when separate functions are activated from different command devices, the control system shall be designed to avoid the operators causing harm to each other or other safety-related objects;

f) before control can be transferred from one command device to another, an explicit changeover action shall be necessary;

NOTE This might include situations in which no command device is active (e.g. when the personal care robot is in a safe state) and any command device is able to take over control.

g) if appropriate, it shall be clearly indicated on all command devices which one is currently active and which is not.

6.9.6 Cableless or detachable command device

If one or more cableless or detachable command devices are available to operate the personal care robot, the following shall apply:

a) in the case of loss of communication, or when correct control signals are not received, any robot being controlled by such a device shall lead to a protective stop if continuing the task can lead to an unacceptable risk;

b) when applicable, the maximum response time for data communication (including error correction) and for loss of communication shall be considered for the calculation for the overall stopping performance (time), and shall be stated in the information for use;

c) on command devices in which emergency stop control devices are integrated, means shall be provided to avoid confusion between active and inactive command devices (e.g. storage of inactive devices in an appropriate location).

6.9.7 Protection against unauthorized use

If necessary, steps shall be taken to prevent unauthorized use of controls or parameter changes, even through remote access. Means (e.g. password protection) shall be provided for preventing any unauthorized use, as determined by risk assessment; for example, use of anti-vandalism methods such as key cards and fingerprint recognition devices to avoid unintended personal care robot starts or moves. The manufacturer should consider different levels of access for different users.

6.10 Operational modes

6.10.1 General

A personal care robot shall be designed to operate in one defined mode at one time. If risk assessment shows that any changeover between two modes is a potential hazard, then the robot shall perform a protective stop immediately prior to that mode change. The selection of the mode shall be indicated unambiguously, and not initiate by itself, robot motion or other hazards.

For all operational modes it shall be clear which safety functions are active and especially which are disabled. When switching between modes, any suspended safety functions shall be returned to their full functionality. When provided for safety-related purposes, the operating mode selection function shall conform to the requirements of 6.1.

Table 10 summarizes the main characteristics of the operational modes of personal care robots.

Table 10 — Characteristics of operational modes of personal care robots

Characteristic	Operational mode			
	Autonomous mode	Semi-autonomous mode	Manual mode	Maintenance mode
Initiation of action	By the robot or the user	By the user	By the user	By an authorized person
Frequency of human intervention	once/rare	frequently	constantly	constantly
Degree of supervision by the human	none/very low	low to high	high	high
Task example	Fetch and carry task for mobile servant robot	Person carrier robot with autonomous navigation capability. Human can override speed and direction	Teaching, tele-operation, programming and program verification	Maintenance
User restriction	none	none	none	Key lock or password protection required.

6.10.2 Autonomous mode

A personal care robot moves automatically or autonomously under this operational mode. The required safety functions for the autonomous mode defined by risk assessment shall be active.

6.10.3 Manual mode

Manual mode shall allow a personal care robot to be operated by human intervention. This mode can be used for teaching, tele-operation, programming and program verification of the robot. Information for use shall contain appropriate instructions and warnings that the operation with manual navigation/guidance is being performed.

A risk assessment shall be carried out to determine which safeguards and protective measures should be active in manual mode to mitigate certain hazards.

6.10.4 Semi-autonomous mode

Semi-autonomous mode shall allow the user to override or change the personal care robot's functions, e.g. steering, hand guiding and human-robot interactive tasks while the robot is performing its task program. In semi-autonomous mode, the autonomous process may also override manual operation, e.g. autonomous collision avoidance function. Risk assessment shall determine the hazards associated with semi-autonomous operation, focusing in particular on how the intervention starts.

When the autonomous process overrides the manual operation the personal care robot shall provide noticeable indication of the override status to the operator. Override indications (e.g. visible light, audible sound, vibrations) shall be designed to be easily recognized by the operator.

NOTE The power assistance by a physical assistant robot is not considered as overriding, whereas the autonomous braking for collision avoidance while the human operator steps on the accelerator is considered as overriding.

The priority of the autonomous process and manual operation shall be determined by risk assessment.

6.10.5 Maintenance mode

If, for maintenance operations, the personal care robot is required to operate with a guard displaced or removed and/or a protective device disabled, a maintenance mode shall be provided. When entering this mode the mode selector shall simultaneously:

a) disable all other control or operational modes;

b) permit operation of hazardous functions only by control devices requiring sustained action (hold-to-run);

c) permit the operation of hazardous functions only in reduced risk (e.g. low speed, low force) conditions while preventing hazards from linked sequences;

d) prevent any operation of hazardous functions by voluntary or involuntary action on the robot's sensors.

Entry into maintenance mode shall only be possible via appropriate means that locks and exclusively enables only this mode; e.g. a key operated switch or other means that provides an equivalent security (e.g. password access).

In addition, the operator shall control any moving parts only by means of actuating controls or command devices that are tethered or attached to the personal care robot. Remote controls (see 6.9.2 and 6.9.3) or cable-less/detachable command devices (see 6.9.6) shall not be used while the robot is in this mode. Cable lengths for tethered controls operating in this mode shall not exceed the maximum length, width or height of the robot (whichever is greatest), if deemed necessary by risk assessment.

If any of the above conditions become invalid during operation with guards removed, or safety functions disabled, the personal care robot shall initiate a protective stop in accordance with 6.2.2.3.

NOTE By fixing a personal care robot to a jig to constrain its motion, maintenance could be possible without switching the robot to the maintenance mode.

Instructions for operation of the personal care robot in this mode, and warnings regarding any hazards related to operation with guards removed, shall be placed in its information for use (see Clause 8).

6.11 Manual control devices

6.11.1 General

Where a command device is realized with manual control devices that initiate power or motion, they shall be designed and constructed to meet the performance criteria mentioned in 6.9.2 to 6.9.6.

6.11.2 Status indication

The status of the manual control devices shall be clearly indicated at all times, e.g. power on, operational mode, fault detected. The status should be indicated in a conspicuous location for the operator.

In the case of remote controls, each command device shall clearly identify the parts of the personal care robot to be controlled from that unit. The remote control system shall be designed and constructed in such a way as to affect only:

— the parts of the robot in question;

— the functions in question.

If an indicator light is used, it shall be meet ergonomic design principles for its installed location and its colour shall meet the requirements of IEC 60204-1.

6.11.3 Labelling

Manual control devices shall be labelled to clearly indicate their function in compliance with ISO 7000.

6.11.4 Protection from unintended operation

Manual control devices shall be designed and constructed so as to prevent unintended operation by following means:

a) when the personal care robot is placed under manual control or remote control, initiation of the robot motion or change of the local control selection shall be exclusively performed from one source;

b) by the use of appropriate designed manual control devices, e.g. shrouded push-buttons, action sequences on touch panels, key selector switches;

c) appropriate placement of manual control devices, so that accidental touching is prevented;

d) where appropriate, different levels of access shall be used to prevent unintended actions or change of settings.

NOTE If access is provided not only “by person” but also “by role”, a trained operator can use a user account with limited access for daily work and only switch to a privileged account when needed.

7 Verification and validation

After the risk reduction process, all of the personal care robot’s performance values related to the safety of the robot shall be verified and validated. This shall include the performance of the control systems with regard to the requirements specified in Clause 6.

All safety requirements shall be verified in accordance with their associated verification standard.

Details of the verification and validation methods listed in 5.1 are described as follows:

— A (inspection): inspecting the condition of the personal care robot or equipment and structures, using human senses without any specialized inspection equipment: inspection is typically carried out visually or acoustically when the robot is not in operation;

— B (practical tests): testing the personal care robot or its equipment under normal and abnormal conditions; functional tests (e.g. fault injection testing), cyclic tests (e.g. endurance testing), performance tests (e.g. braking performance testing);

— C (measurement): compare actual values of personal care robot’s characteristics with specified limits;

— D (observation during operation): inspecting (as in method A) the functions of the personal care robot or equipment during operation under normal and abnormal conditions, e.g. with rated payloads, overloaded situations and under impact conditions;

— E (examination of circuit diagrams): structured review or walk through of the design of circuit diagrams (e.g. electrical, pneumatic, hydraulic) and related specifications;

— F (examination of software): structured review or walk through of the design of software code and related specifications: code inspection or testing of the software code should follow;

— G (review of task-based risk assessment): structured review or walk through of the risk analysis, risk estimation and relevant documentation;

— H (examination of layout drawings and relevant documents): structured review or walk through of the design of layout drawings and relevant documents.

8 Information for use

8.1 General

Information for use consists of information for proper use of a personal care robot. It may not be intended only for the user but also for maintenance personnel.

Instruction and other text required by this International Standard shall be written in an official language of the country in which the personal care robot is to be sold.

Markings, symbols and written warnings shall be readily understandable and unambiguous, especially as regards the part of the function(s) of the robot to which they are related. Readily understandable signs (pictograms) should be used in preference to written warnings. Signs and pictograms should only be used if they are understood in the culture in which the personal care robot is to be sold.

Attention is drawn to the fact that, in a typical environment for personal care robots, not all users are able to read the instruction handbook or to notice and understand acoustic or visual warning sings. This includes, but is not limited to, the following situations and user groups:

a) children, elderly persons, mentally impaired persons;

b) animals;

c) guests/visitors in private areas;

d) third parties near the robot in public areas.

Where it is foreseeable that the information for use will not be available for certain groups of persons, this shall not lead to additional risks.

The markings required by this International Standard shall be clearly legible and durable.

NOTE In considering the durability of the marking, the effect of normal use is taken into account. For example, marking by means of paint or enamel, other than vitreous enamel, on containers that are likely to be cleaned frequently, is not considered to be durable.

Except for information described in 8.2, information for use can be supplied not only with printed material but any electronic media as long as they are easily available in any region where the personal care robot is to be sold.

8.2 Markings or indications

Markings on the personal care robot shall be clearly discernible from the outside of the robot or if necessary after removal of a cover.

At least the name or trademark or identification mark of the manufacturer or responsible supplier, and the model or type reference shall be visible when the personal care robot is in normal use. If a robot is integrated into a building or another framework (e.g. furniture), this requirement applies after the robot has been installed according to the instructions provided with the personal care robot.

Switches and controls shall be clearly marked to cause no confusion.

The following identification shall be marked on the personal care robot:

— the business name and full address of the manufacturer and, where applicable, its authorized representative;

— type/designation of the personal care robot;

— any legally required marking, if applicable;

— designation of series or type of personal care robot;

— serial number, if any;

— the year of construction, i.e. the year in which the manufacturing process is completed.

The following technical information shall be marked on a main part of the personal care robot:

— rated voltage or rated range in volts;

— symbol for nature of supply, unless the rated frequency is marked;

— rated power input in watts or rated current in amperes;

— IP number according to degree of protection against ingress of water, other than IP X0;

— symbol IEC 60417-5172 (2003-02) for personal care robots with Class II construction (as defined in IEC 60335-1);

— symbol IEC 60417-5180 (2003-02) for personal care robots with Class III construction (as defined in IEC 60335-1); this marking is not necessary for personal care robots that are operated only by batteries (primary batteries or secondary batteries that are recharged outside of the personal care robot);

— mass (in kilograms) of the personal care robot itself and/or of removable parts if they are heavier than 10 kilograms.

Units of physical quantities and their symbols shall be in accordance with the International System of Units (SI).

A personal care robot having a range of rated voltage values, and which can be operated without adjustment throughout the range shall be marked with the lower and upper limits of the electrical ratings range.

A personal care robot having different rated voltage values, and which have to be adjusted for use at a particular value by the user or installer shall be marked with the different values.

For a personal care robot marked with more than one rated voltage, or with one or more rated voltage range, the rated power input, or rated current for each of these voltage or a ranges shall be marked. However, if the difference between the limits of a rated voltage range does not exceed 10 % of the arithmetic mean value of the range, the marking for rated power input or rated current may be related to the arithmetic mean value of the range. The upper and lower limits of the rated power input or rated current shall be marked on the personal care robot so that the relation between input and voltage is clear.

If symbols are used for markings, they shall conform to the requirements in IEC 60417-1, IEC 60204-1 or ISO 7010; some examples are presented in Annex E.

NOTE 1 It is observed that there is some inconsistency with regard to meanings of symbols between these standards. For example, symbol IEC 60417-5007 (DB:2002-10) means only “ON” (power), whereas the same symbol means “START or ON” in IEC 60204-1.

For switch markings, their different positions on personal care robots connected to the supply mains, and the different positions of controls on all personal care robots shall be indicated by figures, letters or other visual means. This requirement also applies to switches which are part of a command device.

If figures are used for indicating the different positions, the off position shall be indicated by the numeric character “0” and the position for a higher value (e.g. output, input, speed or cooling effect) shall be indicated by a higher character number.

The character “0” shall not be used for any other indication unless it is positioned and associated with other numbers so that it does not give rise to confusion with the indication of the off position.

For signals and warning devices, visual signals (e.g. flashing lights) and audible signals (e.g. sirens) may be used to warn of an impending hazardous event (e.g. personal care robot start-up or overspeed). Such signals may also be used to warn the operator before the triggering of automatic protective measures.

These signals shall:

a) be unambiguous and clearly differentiable from all other signals used, and

b) be clearly recognizable to the operator and other persons.

The warning devices shall be designed and located such that checking is easy. The information for use shall prescribe regular checking of the warning devices as appropriate.

The attention of designers is drawn to the possibility of "user overload", which can result from too many signals, leading to confusion that might defeat the effectiveness of the warning devices.

NOTE 2 Consultation with the users is often necessary.

For replaceable protective devices, if compliance with this International Standard depends upon the operation of a replaceable thermal link or a fuse link, the reference number or other means for identifying the link shall be marked at such a place that it is clearly visible when the personal care robot has been dismantled to the extent necessary for replacing the link.

NOTE 3 Marking on the link is permitted, as long as the marking is legible after the link has functioned.

This requirement does not apply to links which can only be replaced together with a part of the personal care robot.

8.3 User manual

A user manual shall be provided with the personal care robot so that it can be used as intended. The user manual shall contain among others the following:

a) detailed description of the personal care robot;

b) the comprehensive range of applications for which the personal care robot is intended, including prohibited usages, if any, taking into account variations of the original personal care robot if appropriate;

c) command devices;

d) setting and adjustment;

e) modes and means for stopping (especially emergency stop);

f) particular risks, including residual risks, which can be generated by certain functions, by the use of certain fittings, and about specific safeguards necessary for such functions;

g) reasonably foreseeable misuse and prohibited applications such as playing with the personal care robot by children;

h) fault identification and location, for resetting and for restarting after an intervention;

i) the operating method to be followed in the event of accident or breakdown;

NOTE Instructions for use can be marked on the personal care robot, as long as they are visible in normal use.

If it is necessary to take precautions during user maintenance, appropriate details shall be given.

The instructions for personal care robots incorporating batteries that are intended to be replaced by the user shall include the following:

— the type reference of the battery;

— the correct charging procedure/equipment;

— the method of replacing batteries;

— details regarding safe disposal of used batteries;

— warning against using non-rechargeable batteries;

— warning against mistreatment of batteries (e.g. deep discharge of lithium batteries);

— how to deal with leaking batteries.

If it is necessary to take precautions during installation of the personal care robot, appropriate details shall be given. When the installation is intended to be performed by maintenance personnel only, this information shall be contained in a service manual.

Instruction for use shall contain information relating to transport, handling and storage of the personal care robot, e.g.

— mass value(s), position of the centre(s) of gravity;

— indications for handling (e.g. drawing indicating application points for lifting equipment);

— environmental conditions for storage.

Information relating to dismantling, disabling and scrapping the personal care robot shall be provided.

8.4 Service manual

The service manual shall contain instruction for maintaining/resupplying the personal care robot which require a definite technical knowledge or particular skills, and hence need to be carried out exclusively by skilled persons (e.g. maintenance staff, specialists).

Maintenance instructions provided for skilled persons and maintenance instructions provided for unskilled persons need to appear clearly separated from each other.

Maintenance instructions shall contain sufficient information to maintain the same level of safety, quality and functionality of the personal care robot.

The information provided with the personal care robot shall include where necessary the following:

a) a clear, comprehensive description of the equipment, installation and mounting, and the connection to the power supply/supplies;

b) power supply requirements;

c) information on the physical environment (e.g. lighting, vibration, noise levels, atmospheric contaminants), where appropriate;

d) information (as applicable) on:

   — programming, as necessary for setting up, use or maintenance of the personal care robot;

   — sequence of operation(s);

   — frequency of inspection;

   — frequency and method of functional testing;

   — guidance on the adjustment, maintenance, and repair, particularly of the protective devices and circuits;

   — recommended spare parts list;

   — list of tools supplied.

e) a description (including interconnection diagrams) of the safeguards, interlocking functions, and interlocking of guards against hazards, particularly for multiple personal care robots operating in a coordinated manner;

f) a description of the safeguarding and of the means provided where it is necessary to suspend the safeguarding (e.g. for setting or maintenance);

g) instructions on the procedures for securing the robot for safe maintenance;

h) information regarding load currents, peak starting currents and permitted voltage drops, as applicable;

i) information on the residual risks due to the protection measures adopted.

Annex A
(informative)

List of significant hazards for personal care robots

One of the essential steps in performing a risk assessment, as described in ISO 12100, is a hazard identification analysis.

This form of analysis is a systematic procedure to identify potential hazards that can be caused by a system or machine, based on some aspect of its general specification. Systematic procedures can involve analysis of its functional specifications or interfaces, of hazards experienced with similar products already developed, or they may use comprehensive sets/lists of generic hazard types.

Given the wide range of possible applications of personal care robots, it is not practicable to produce a single list of hazards that can provide comprehensive coverage of all relevant hazards. However, it is possible to provide a minimum list of hazards that all applications should cover in their results.

For all personal care robots covered by this International Standard, a combined list has been provided in Table A.1 as a recommendation for the minimum coverage that should be achieved by any given hazard identification exercise. The results of the specific hazard identification methodology should be compared with the list. If the results are found not to cover the entire set of hazards in the list, the hazard identification results should be extended or augmented to cover the remaining hazards.

Table A.1 — Hazards for personal care robots

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
1.	Battery charging hazards	Battery overload	Fire, discharge of hazardous fumes or substances	5.2	
2.		Charging of deeply discharged batteries	Fire, discharge of hazardous fumes or substances	5.2	
3.		Contact with live battery terminals	Electric shock	5.2	
4.		Battery short-circuit	Fire, discharge of hazardous fumes or substances	5.2	

Table A.1 *(continued)*

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
5.	Energy storage and supply hazards	Harmful contact with high electrical energy sources	Electric shock, burning	5.3.1	
6.		Electrical components/parts becoming live under fault conditions	Electric shock	5.3.1	
7.		Harmful contact with high mechanical energy sources	Crushing, cutting, trapping, burning	5.3.1	High energy mechanical parts include rotating/ fast-moving parts, high pressure hydraulics or pneumatics, fuel-burning sub-assemblies
8.		Harmful contact with high pneumatic energy sources	Crushing, cutting, trapping, injection	5.3.1	
9.		Harmful contact with high hydraulic energy sources	Crushing, cutting, trapping, injection	5.3.1	
10.		Harmful contact with high chemical energy sources	Burns, irritation	5.3.1	
11.		Harmful contact with high temperature/high thermal energy sources	Burns	5.3.1	
12.		Uncontrolled release of stored energy (rapid discharge, explosion)	Fire, burn injuries, crushing, stabbing, cutting	5.3.2	Stored energy can occur in pneumatic and hydraulic pressure accumulators, capacitors, batteries, springs, counter-balances, flywheels, etc.
13.		Power failure	Crushing, trapping, dropped loads, runaway,	5.3.3	
14.		Unintended shutdown	Crushing, trapping, dropped loads	5.3.3	
15.		Power overload	Fire	5.3.3	
16.		Partial power failure (brownouts)	Other hazards	5.3.3	
17.		Harmful electrostatic discharge	Electric shock	5.5.1	
18.	Hazards due to robot start-up	Unintended/ unexpected start-up	Other hazards	5.4	
19.		Hazardous actions taken during start-up or restart	Other hazards	5.4	
20.	Hazards due to robot shape	Sharp edges	Cutting, severing, stabbing, abrasion	5.6	
21.		Holes or gaps between moving parts	Crushing, trapping, pinching, cutting, severing, abrasion	5.6	
22.		Hazardous detachment/ dropping of parts	Crushing, trapping	5.6	
23.		Hazardous robot shape profile during collisions	Impact injuries, crushing, trapping, cutting	5.6	
24.	Hazards due to noise	Harmful levels of acoustic noise	Hearing loss, stress, discomfort, loss of balance, loss of consciousness	5.7.1	
25.		Robot emits harmful ultrasonic emissions	Hearing loss, stress, discomfort, loss of balance, loss of consciousness	5.7.1	

Table A.1 *(continued)*

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
26.	Hazards due to lack of awareness	Lack of noise/silent operation	Collisions with humans (causing impact injuries) or other safety-related obstacles	5.14	This hazard should also be considered if a personal care robot might have any users with hearing difficulties and might therefore be unaware of a robot even though it does make noise. Not applicable to restraint-type physical assistant robots.
27.	Hazardous vibration	Harmful levels of vibration	Tendon inflammation, backache, discomfort, neurosis, arthritis, motion sickness, and other vibration-related injuries	5.7.2	
28.		Reduced legibility of displays due to vibration	Harmful events caused by incorrect user action or loss of user control	5.7.2	
29.	Hazardous substances and fluids	Contact with harmful substances/fluid emissions from the personal care robot (e.g. hydraulic fluid)	Burns, irritation, sensitization	5.7.3	
30.		Volatile solvents, fumes emitted by the personal care robot	Sensitization, irritation, asphyxiation, blinding	5.7.3	
31.		Allergic response to contact with robot surfaces	Irritation, sensitization	5.7.3	
32.	Hazardous environmental conditions	High levels of dust	Fire, other hazards	5.15	To be considered if a personal care robot is intended to operate: - in household environments - in the presence of high quantities of powder or finely granulated materials (e.g. kitchens) - if the robot is intended to operate for long periods between maintenance inspections.
33.		Sand	Abraded surfaces causing sharp edges; jamming of moving parts causing unsafe poses/configurations; degraded braking performance causing collisions	5.15	To be considered if a personal care robot is intended to operate in outdoor environments.
34.		Exposure of personal care robot to snow, ice	Jamming of moving parts, short circuit hazards, incorrect action due to sensor interference, other hazards	5.15	To be considered if a personal care robot is intended to operate in winter environments or cold zones.
35.		Exposure of personal care robot to water, moisture	Short circuit causing functional failure(s), fire, loss of power	5.15	To be considered if a robot is intended to operate in outdoor environments or near bodies or sources of water or sprays.
36.		Exposure of robot to saline atmosphere or salt-water sprays (e.g. in marine or coastal environments)	Structural failure, other hazards caused by corrosion-induced functional failures, battery/power supply failure, short-circuit hazards	5.15	To be considered if a personal care robot is intended to operate in outdoor environments near oceans, seas or other salt-water bodies (or on board boats or ships).

Table A.1 *(continued)*

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
37.	Extreme temperatures	Hot surfaces	Burns, stress, discomfort	5.7.4	
38.		Cold surfaces	Burns, chilblains, stress, discomfort	5.7.4	
39.		Reduced legibility of displays	Harmful events caused by incorrect user action or loss of user control	5.7.4	
40.	Hazardous non-ionising radiation	Robot emits harmful non-coherent optical radiation	Burns, ocular injuries	5.7.5	
41.		Robot emits harmful coherent optical (laser) radiation	Ocular injuries (blind spots, full blindness)	5.7.5	Not applicable to restraint-type physical assistant robots.
42.		Robot emits harmful levels of EMI	Hazardous effects on medical implants/devices, hazardous effects on external machinery, electronic systems, hazardous effects on infrastructure control systems (e.g. transportation, electricity distribution, lighting systems, telecommunications)	Not within scope of this International Standard. Refer to EMC standards (e.g. IEC 61000 series) for relevant requirements	
43.	Hazardous ionising radiation	Robot emits harmful levels of ionising radiation	Radiation sickness, effects on reproductive capacity, mutation	5.7.6	Ionising radiation sources should not be employed in personal care robots unless there is no alternative for the robot's intended application. All uses of ionising radiation should be subject to a separate specific risk assessment.
44.	EMI/EMC hazards	Loss of safety function due to external EMI	As defined for each function	5.8	To be considered for all safety functions of the personal care robot
45.		Inadvertent operation of function induced by external EMI	As defined for each function	5.8	To be considered for all functions of the robot (both application/service functions and safety functions) Consequences and affected areas are as determined by functional hazard analysis (see item 66)
46.		Hazardous personal care robot motion induced by external EMI (e.g. runaway, unintended arm movements)	Crushing, trapping, impact, collision, cutting, severing,	5.8	
47.		Unsafe robot state induced by external EMI	Crushing, trapping, impact, cutting, severing, fire, burns	5.8	

Table A.1 *(continued)*

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
48.	Stress, posture and usage hazards	Stressful posture required for robot operation	Musculoskeletal disorder	5.9.2	
49.		Operational environments causing physical discomfort	Fatigue Muscular strain or inflammation	5.9.2	Fatigue might be caused by continuous exposure to uncomfortable levels of sound/noise, light, heat, or other factors
50.		Incorrect user body size assumptions	Stressful body posture, user fatigue, muscular injury/disorder	5.9	
51.		Poor user interface design and/or location of indicators and visual displays units	Discomfort due to user misunderstanding of personal care robot	5.9.3	
52.			Slow response of user in hazardous situations	5.9.3	To be considered for all safety functions requiring timely user actions via the user interface
53.			Excessive false positive alarms, causing users to ignore/switch off alarms and leading to failures to respond to alarm signals	5.9.3	
54.			Poor control-display relationships, causing incorrect/inappropriate user responses	5.9.3	Where users have a worsening condition, consideration shall be given to their changing performance as well
55.		Poor visibility of personal care robot	Occurrence of other hazards as a consequence of human error	5.9	

Table A.1 *(continued)*

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
56.	Hazards due to robot motion	Mechanical instability (overturning, falling, excessive leaning)	Crushing, trapping, dropped loads	5.10.2	
57.		Mechanical instability – overturning while handling loads	Crushing, trapping, dropped loads	5.10.2	
58.		Travel instability – rollover during basic travel pattern	Crushing, trapping, cutting/ severing, dropped loads	5.10.3	Basic travel patterns include: - forward/ backward travel - rotation - turns/u-turns - acceleration - deceleration Not applicable to restraint-type physical assistant robots.
59.		Travel instability – runaway during basic travel pattern	Collision, dropped loads, damage to environment	5.10.3	
60.		Travel instability - rollover due to passenger in incorrect position	Crushing, trapping, cutting/ severing, dropped loads	5.10.3	Applicable only to person carrier robots
61.		Instability while carrying loads – safety-related objects falling or dropped while performing tasks	Damage to environment, release of harmful substances, burning (for hot fluids), cutting/severing (for sharp objects)	5.10.4	
62.		Instability in collision – rollover or overturning following collision	Crushing, trapping, cutting/ severing, dropped loads	5.10.5	Not applicable to restraint-type physical assistant robots.
63.		Instability in collision – runaway following collision	Collision, dropped loads, damage to environment	5.10.5	Not applicable to restraint-type physical assistant robots.
64.		Detachment of body parts following collision	Crushing, trapping	5.10.5	
65.		Instability while attaching a restraint-type physical assistant robot	Crushing, trapping, impact injuries	5.10.6	Applicable only to restraint-type physical assistant robots
66.		Instability while removing a restraint-type physical assistant robot	Crushing, trapping, impact injuries	5.10.6	Applicable only to restraint-type physical assistant robots
67.		Rollover during passenger embarkation/ disembarkation	Passenger falls and sustains injury, crushing, trapping	5.10.7	Applicable only to person carrier robots
68.		Runaway during passenger embarkation/ disembarkation	Passenger falls and sustains injury, crushing, trapping	5.10.7	Applicable only to person carrier robots

Table A.1 *(continued)*

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
69.	Collision with safety-related obstacles	Collision with safety-related objects	Blunt force trauma, cutting/ severing injuries	5.10.8	Not applicable to restraint-type physical assistant robots.
70.		Collision with domestic animals	Injury to (or fatality of) animals Animal panicking with subsequent injuries to humans or damage to the environment	5.10.8	Responses of animals might include: - animals biting the robot - animals trampling the robot - animals fleeing the robot in fear - animal shock or distress due to the presence of the robot - animals injured by the task actions of the robot Not applicable to restraint-type physical assistant robots.
71.		Collision with other robots	Crushing, trapping, dropped loads	5.10.8	Not applicable to restraint-type physical assistant robots.
72.		Collision with fragile safety-related objects	Damage to the environment, dropped loads, release of harmful substances, burning (for hot fluids), cutting/severing (for sharp safety-related objects)	5.10.8	Not applicable to restraint-type physical assistant robots.
73.		Collision with walls, permanent/ unmovable barriers	Damage to environment, release of harmful substances, burning (for hot fluids), cutting/severing (for sharp safety-related objects)	5.10.8	Not applicable to restraint-type physical assistant robots.
74.	Hazardous physical contact during human-robot interaction	Failure to detect safety-related objects in workspace	Collision with safety-related objects (see item 62)	5.10.9	To be considered for all functions and tasks (service/application-related and safety-related) Not applicable to restraint-type physical assistant robots.
75.		Harmful physical reaction levels during tactile interaction	Cutting/severing, crushing, trapping	5.10.9	To be considered for all planned tactile human-robot interaction tasks. The following physical parameters of the interaction should include the following, (where relevant): - skin-robot friction - shear stress - dynamic shock - torque - arcs of centre of gravity - weight-bearing transfers - support for the human body
76.		Tactile interaction with robot parts not intended for tactile interaction	Blunt force injuries, trapping, crushing	5.10.9	

Table A.1 *(continued)*

No	Hazard item	Hazard analysis		Associated safety requirement clause	Remarks
		Hazard	Potential consequence		
77.	Insufficient durability	Robot part failure due to insufficient durability	Other hazards	5.11	To be considered for all functions and tasks. Lack of durability might include (where relevant): - mechanical stress/ fatigue - thermal cycling/fatigue - materials and their properties - vibration and other emissions - environmental conditions (normal and adverse) - normal operation - foreseeable abnormal operation (unexpected travel patterns, loads) - foreseeable misuse (e.g. overloading, vandalism)
78.	Hazardous autonomous action	Harmful action taken in performing tasks	Other hazards	5.12	A functional hazard identification analysis is required for all personal care robot functions and tasks (both safety-related and service/ application-related)
79.	Hazardous contact with moving parts	Harmful contact with moving mechanical parts	Drawing-in, trapping, crushing, cutting	5.13	
80.	Hazards due to localization and navigation errors	Localization errors causing unexpected movement of the personal care robot	Crushing, trapping, impact injury, dropped loads	5.16	
81.		Localization errors causing entry of forbidden zone	Collision, crushing, trapping, impact injury, dropped loads	5.16	
82.		Localization errors causing mechanical instability	Rollover, crushing, trapping, dropped loads	5.16	
83.		Navigation errors preventing reaching of goal locations or avoiding safety-related obstacles	Collision, crushing, trapping, impact injuries, damage to environment	5.16	
84.	Other hazard items	Poor/inappropriate instructions and training material	Harmful events caused by user error or incorrect action	All	
85.		Reduced user control capabilities due to wearing outdoor clothing, including gloves, hats, sunglasses, boots	Reduced sensations, less accurate control, leading to harmful events caused by user error or incorrect action	All	

Annex B
(informative)

Examples of operational spaces for personal care robots

B.1 Mobile autonomous person carrier (person carrier robot)

A person carrier robot of 200 kg is moving autonomously around in a museum. The walls of the rooms define the maximum space. The floor plan of the working area of the robot has been prepared from the museum floor plan. The robot has a work volume and movable, extending, robot arm parts that should not touch walls. This defines the restricted space. See Figure B.1.

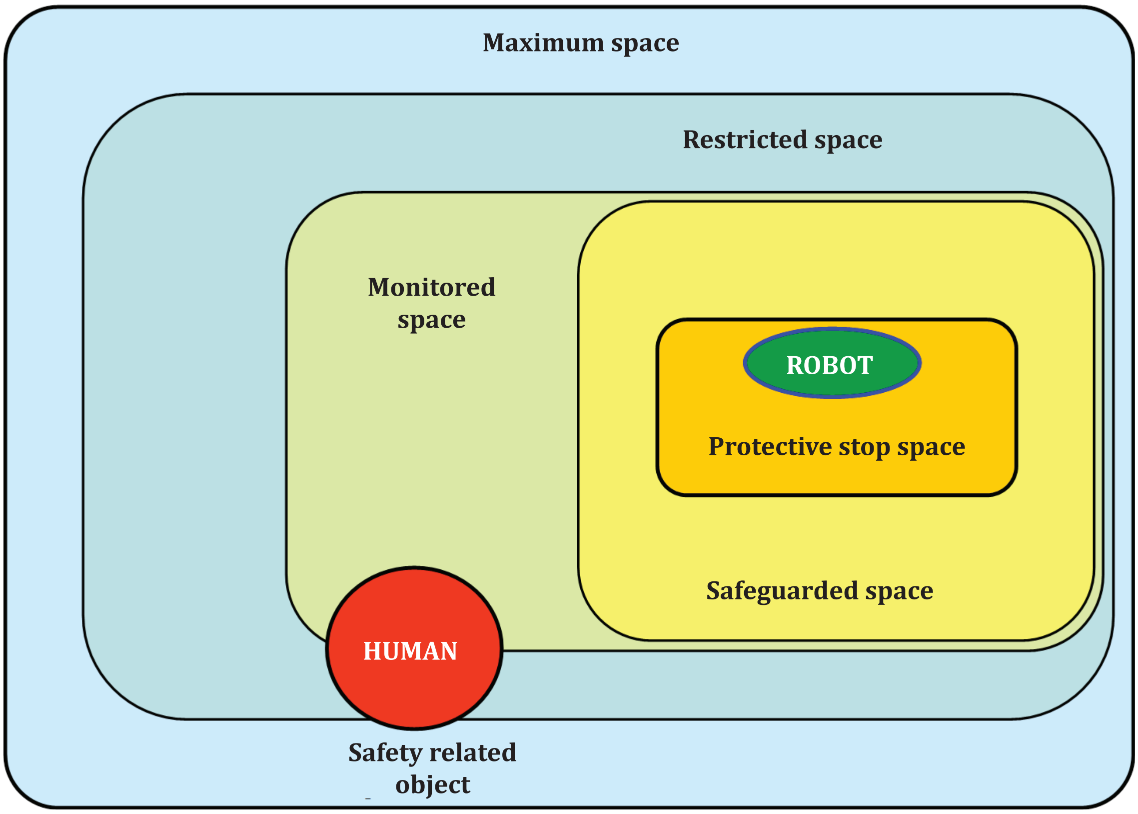


Figure B.1 — Operational spaces of an autonomous person carrier robot

a) The robot is only allowed in the central area of the rooms and doorways. While the robot moves autonomously, it observes the environment with its on-board sensors and via facility-mounted sensors defining the dynamic monitored space.

b) While the robot moves about the room, it dynamically updates its safeguarded space and its protective stop space. As soon as a safety-related object enters the safeguarded space, the robot will reduce its speed depending on actual velocities of the robot and safety-related objects in its environment, thus maintaining safe margins to any safety-related object.

c) If a safety-related object enters into the protective stop space, the robot comes to a protective stop. For this type of robot, it is important that the monitored space overlaps and covers at least the safeguarded space to ensure that the robot has all required information to plan its motions such that no collisions or dangerous situations arise.

d) If a safety-related object is suddenly moving into the safeguarded space of the robot, the robot path planner issues a robot command to react immediately by recalculating a path around the moving safety-related object or stops the robot dependent upon their relative velocities.

B.2 A manipulator-type personal care robot (mobile servant robot)

This case is comparable to an industrial robot application. The maximum space is defined by the maximum extension of the stationary robot arm and the robot has to collaborate with a human within its maximum space.

Two cases can be distinguished for this personal care robot.

a) Manual operation: the robot is completely hand guided so that the operator has full control and manipulates all robot motion. No sensors are needed and no space definitions apply.

b) Semi autonomous operation: the operator just indicates that a certain action should be executed. The robot uses sensors, and some form of path planning to perform the requested operation. The operator has control over the safety-related functions, but might be too late to react. The robot has to use sensors to identify the target (which might be a human) and the position where to perform the intended task. The receiving human is within the maximum space.

The safeguarded space is defined in the same area, where safe interaction between a safety-related object and the robot is possible at a reduced (safe) speed. The sensors actively guard the position of the safety-related object and the robot. The control might adapt the safeguarded space and the protective stop space if the safety-related object moves and the robot turns out to be in the protective stop space, the robot comes to a protective stop. See Figure B.2.

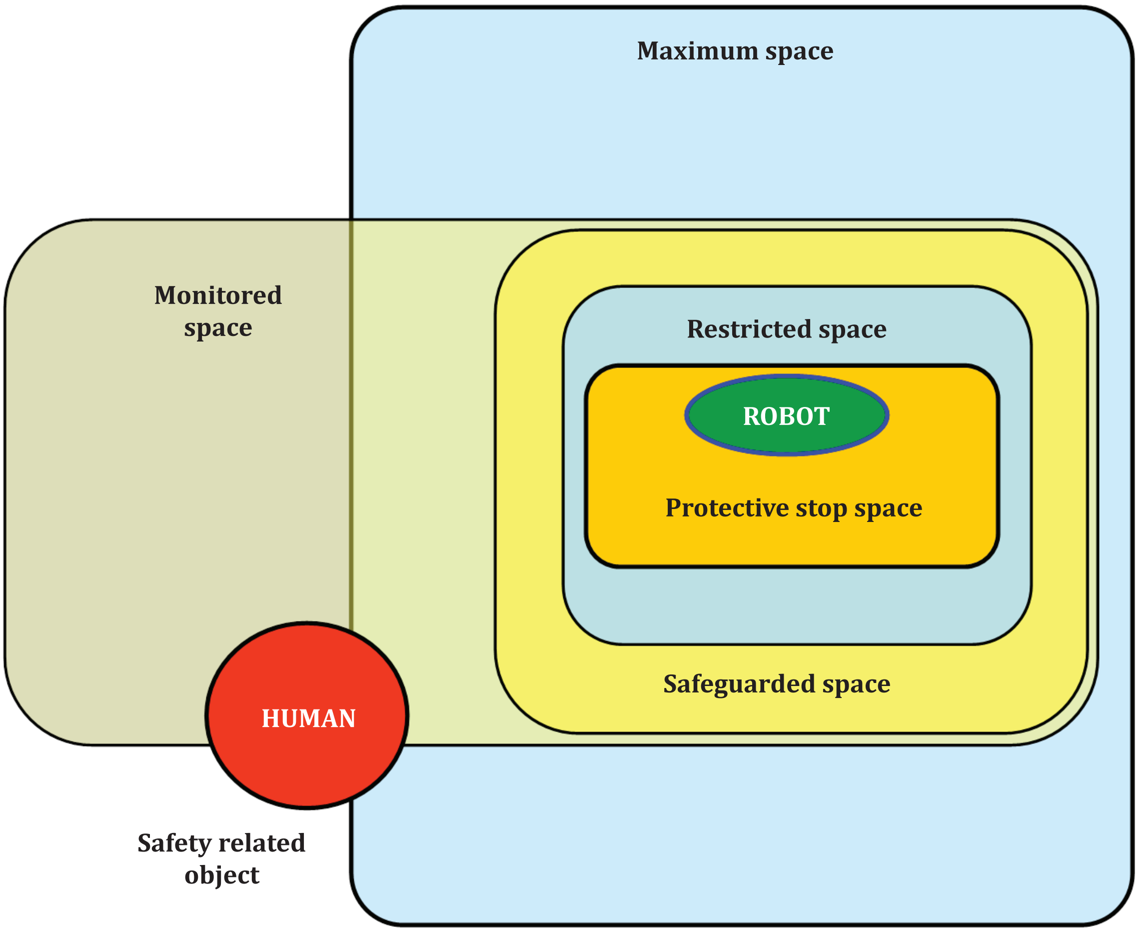


Figure B.2 — Operational spaces of a personal care robot with manipulator

B.3 Exoskeleton (physical assistant robot)

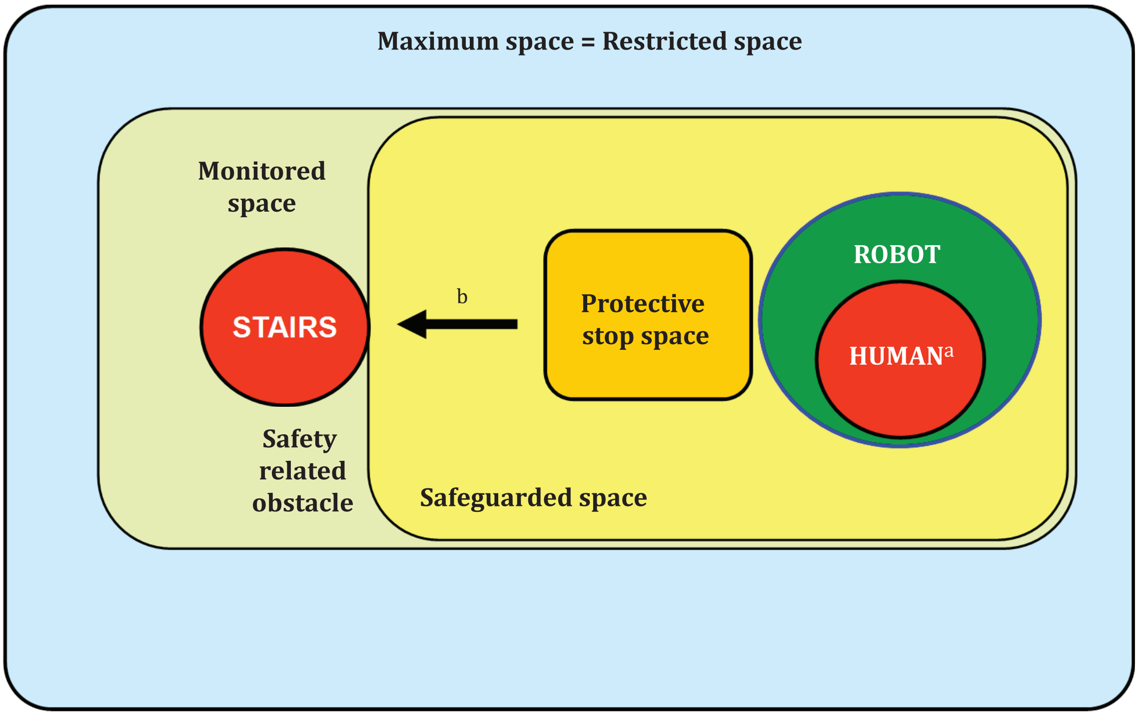
A healthy person is using an exoskeleton to reduce his/her physical work load.

Two cases might exist.

a) Manual control: the user of the exoskeleton controls all movements of the robot (suit). No environmental sensors might be needed.

b) The robot suit is equipped with environmental sensing covering the monitored space, e.g. to avoid that the person wearing the exoskeleton accidently walks down the stairs (safety-related obstacle). The suit can control/influence the operator. There is no maximum space defined for this application, as the person carrying the robot determines where to go. The position of the forbidden area (stairs and other safety-related obstacle) is dynamically updated in the control system of the robot while the robot moves. As a result, the safeguarded space and the protective stop space are permanently recalculated while the operator/robot moves. If a safety-related object enters the safeguarded space, it will signal the operator and reduce support in such a way that the operator safely reduces his/her speed. If the robot enters the protective stop space the robot stops safely, allowing the operator only to move in a different direction, than toward the stairs.

See Figure B.3.



Key

a safety-related object

b momentary direction of movement

Figure B.3 — Operational spaces of a physical assistant robot

Annex C
(informative)

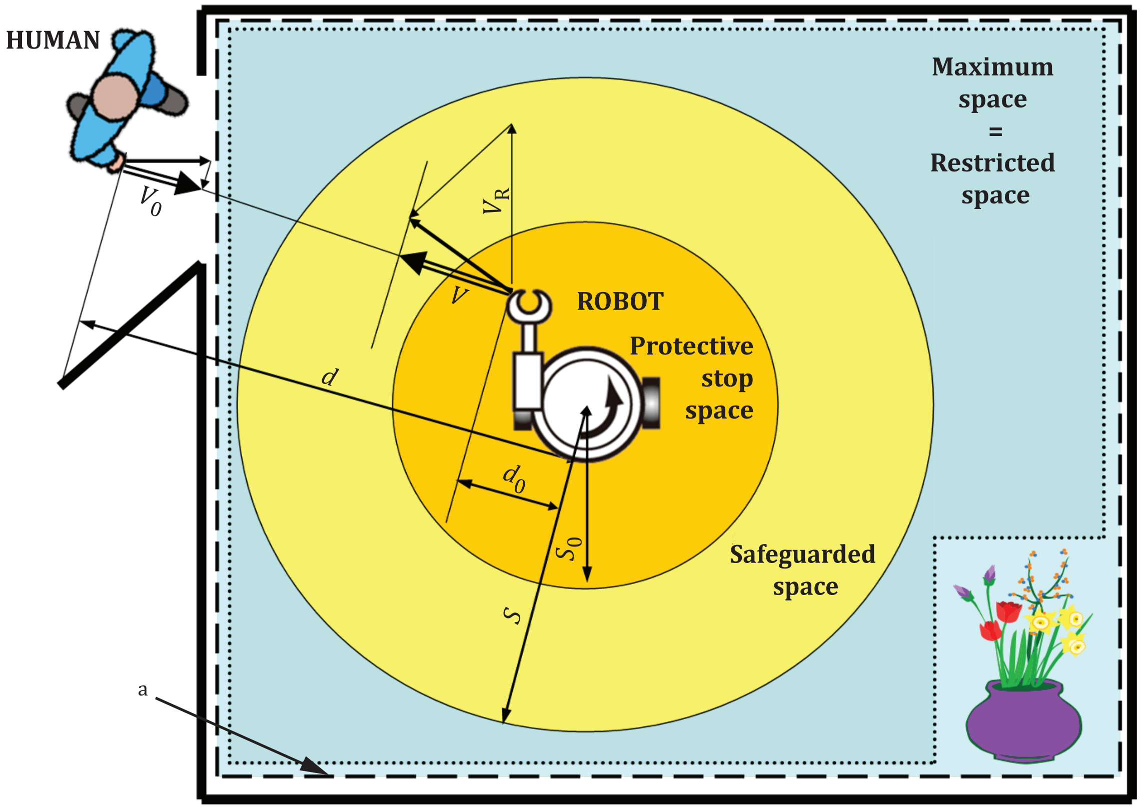
Example of the implementation of a safeguarded space

This annex introduces an example application of personal care robot, based on definitions 3.18.1 to 3.18.5 of safety-related spaces and Figure 1, with typical safeguarding measures taken while achieving the goals of the human-robot coexistence systems. The example is concerned with collision avoidance as stated in 5.10.8. The same safety-related space definitions are applied in these applications.

Figure C.1 shows a mobile personal care robot with a manipulator which possesses an obstacle avoidance capability using safety-related speed control. A relative speed is accounted for in this application. It is possible to compute, by taking the net detected approaching speed of the object v_O into account, the velocity of the robot v_R, from the angular speed ω and the speed component of the robot v_{req} in the safety-related obstacle's approach direction which satisfies Equation (C.1):

$$v_{req} \leq \frac{d - S_O}{T} - v_O \text{, when } d - S_O > 0 \tag{C.1}$$

where T is the system response time required for detecting the velocity of the surrounding safety-related obstacle and reducing the velocity of the robot, d is the distance of the safety-related obstacle from the robot (centre), and the minimum distance S_O is calculated as described in 5.10.8.3 a). Note at this point that if the robot is controlled in a rigorous manner to keep the reference distance from a safety-related object, it might end up with being controlled to back up when the safety-related object approaches it at such a relative speed to result in the condition of $\frac{d - S_O}{T} < v_O$. Finally, when the safety-related obstacle further approaches to the robot at a distance of $d = S_O$, the robot is controlled to make a protective stop. The motion of both the robot and a surrounding safety-related obstacle can be represented in vector form. Moreover, it is needless to say that in the safeguarded space, the robot speed shall be kept to be reduced to an elaborately predetermined small amount $v_{\min}$ if the robot system cannot detect the velocity of the safety-related obstacle successfully.

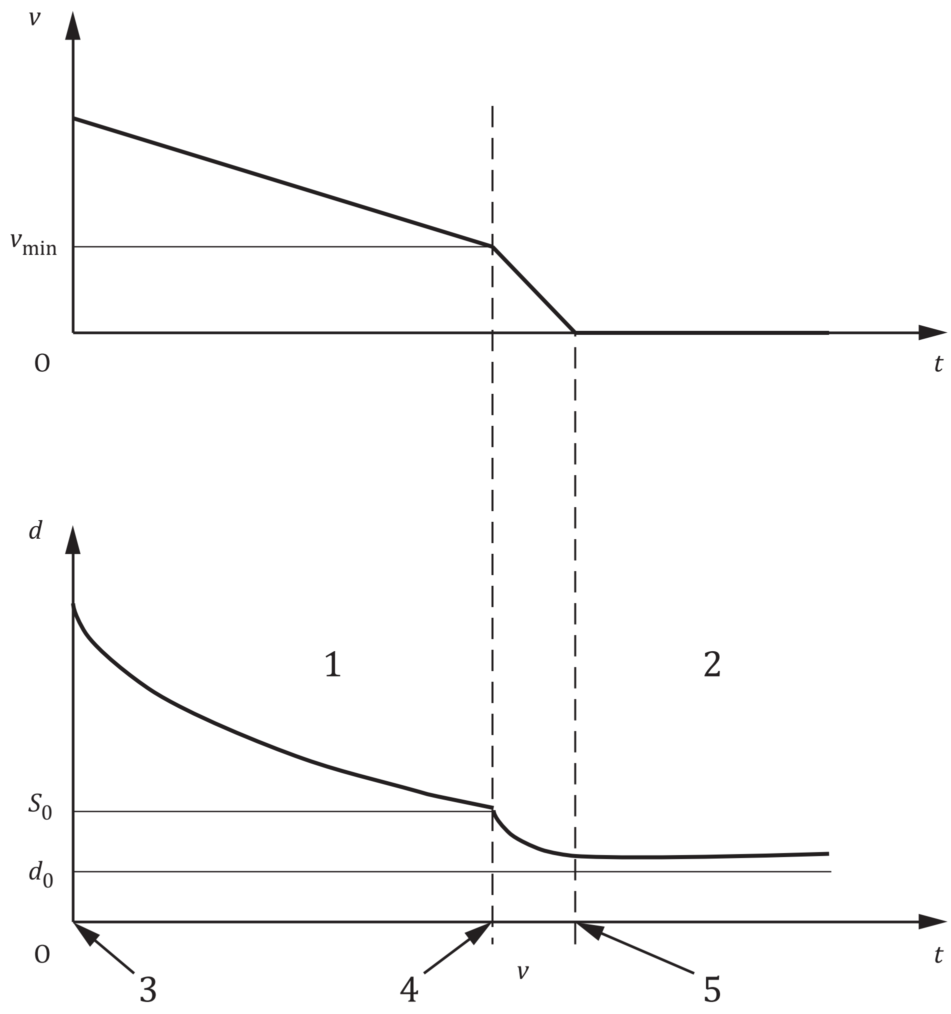


Key

a maximum space

Figure C.1 — Personal care robot application with a manipulator on a mobile platform

The robot speed pattern and the distance of the safety-related obstacle during a safeguarding activation of the obstacle avoidance are shown in Figure C.2. It is possible to change v according to Equation (C.1) if $d - S_o > 0$. The deceleration in the interval Δt might be nonlinear and can vary depending on environmental conditions such as temperature and humidity. In the case of a linear deceleration, a safe stop is reached after an additional path length of $\Delta d = 0.5 \times v_{\min} \times \Delta t$.



Key

1 safeguarded space
2 protective stop space
3 activation of a safeguard
4 activation of braking
5 safe stop

Figure C.2 — Safety distance and maximum relative speed in the safeguarded space

Annex D
(informative)

Examples of functional tasks of personal care robots

Tables D.1, D.2 and D.3 provide examples of functional tasks of personal care robots.

Table D.1 — Mobile servant robots

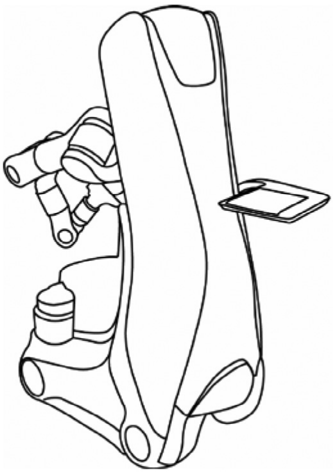
Class of mobile servant robot	Functional tasks that need to be performed
Mobile servant robot in domestic environments or public buildings 	Travelling in domestic environments or public buildings while avoiding collisions with stationary and moving safety-related obstacles. This might include pose-to-pose motion and full area coverage. Interaction with humans including object exchange. The robot can have an active or passive role. Handling of small and medium-sized objects (e.g. coffee cup, plate, book) including grasping, manipulating, transporting, placing and handing over the object. Handling large objects possibly having constraints, e.g. opening a door, a window, a drawer, a dish-washer, which might include travelling in order to extend the workspace.

Table D.2 — Physical assistant robots

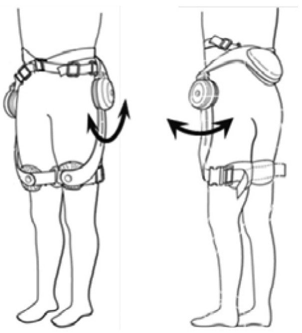
Class of physical assistant robot	Functional tasks that need to be performed
Leg motion assistive device 	Applying cooperative control to user's thighs in order to control the stride and to achieve comfortable walking.

Table D.2 *(continued)*

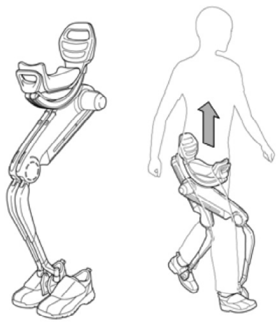
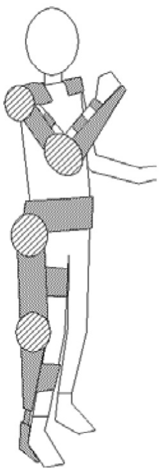
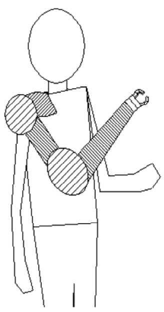
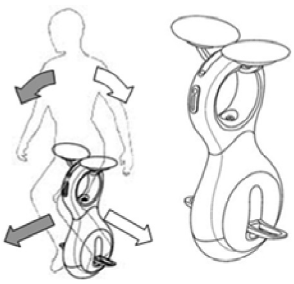
Class of physical assistant robot	Functional tasks that need to be performed
Body weight supportive device 	Reducing the load on leg, hip, knees, and ankles while standing or walking by supporting part of the user's bodyweight.
Exoskeleton wearable robot 	Physically supporting a human and manipulating body parts through direct interaction and fixtures to a person, e.g. straps or clamps. Enabling the user to carry loads similar to or above average human strength.
Wearable robot 	Providing fixture directly to a human without invasion, e.g. straps and clamps to provide direct interaction for dexterous manipulation. Enabling the user to carry loads similar to that of an able bodied person.
Restraint-free assistance robot 	To assist elderly/tired person to and from chair, bed, etc. To assist in basic mobility tasks on flat ground with or without help from partner To help provide more ease and comfort in daily life for independent living

Table D.3 — Person carrier robots

Class of person carrier robot	Functional tasks that need to be performed
Carrier with passenger standing on the foothold 	Physically transporting a person from one location to another on smooth surface, either in autonomous mode or manual mode, using wheeled mobile platform. The travel direction is controlled by shifting the passenger's weight on the base foothold.
Legged passenger carrier 	Physically transporting a person from one location to another on any 3D surfaces, either autonomous mode or manual mode, using legged mobile platform.
Carrier whose passenger sits on a monocycle 	Physically transporting a person from one location to another on smooth surface, either autonomous mode or manual mode, using a wheeled mobile platform. The travel direction is controlled by shifting the passenger's weight.
Wheeled passenger carrier 	Physically transporting a person from one location to another on smooth surfaces, either autonomous mode or manual mode, using a wheeled mobile platform.

Annex E
(informative)

Examples of markings for personal care robots

Table E.1 provides examples of markings of personal care robots.

Table E.1 — Examples of safety and other markings for personal care robots

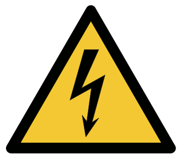
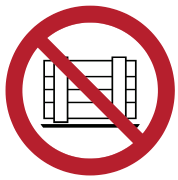
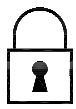
ISO 7010-W001  General warning To signify a general warning	ISO 7010-W08  Drop (fall) To warn of a drop	ISO 7010-W012  Electricity To warn of electricity
ISO 7010-W017  Hot surface To warn of a hot surface	ISO 7010-W018  Automatic start-up To warn of automatic activation	ISO 7010-W019  Warning: Crushing To warn of moving mechanical parts
ISO 7010-W022  Sharp element To warn of a sharp element	ISO 7010-W024  Crushing of hands To warn of closing motion of mechanical parts of equipment	ISO 7010-W025  Counter-rotating rollers To warn of possibility of drawing in
ISO 7010-W026  Battery To warn of hazards related to batteries	ISO 7010-M012  Use handrail	ISO 7010-M021  Disconnect before carrying out maintenance or repair

Table E.1 — *(continued)*

ISO 7010-P011  Do not extinguish with water	ISO 7010-P012  No heavy loads	ISO 7010-P015  No reaching in
ISO 7010-P017  No pushing	ISO 7010, P018  No sitting	ISO 7010-P019  No stepping on surface
ISO 7010-P021  No dogs	ISO 7010, P022  No eating or drinking	ISO 7010-P023  Do not obstruct
ISO 7010-P024  Do not walk or stand here	ISO 7010, P031  Do not alter the state of the switch	
IEC 60417-1  To indicate a “speak” facility	IEC 60417-1  To identify a control to check the condition of the battery	IEC 60417-1  To identify on a control that a function is in the locked status

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