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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

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

Introduction

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

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

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

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

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

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

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

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

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

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

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

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

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

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

Robots and robotic devices — Safety requirements for personal care robots

1 Scope

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

— mobile servant robot;

— physical assistant robot;

— person carrier robot.

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

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

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

This International Standard is limited to earthbound robots.

This International standard does not apply to:

— robots travelling faster than 20 km/h;

— robot toys;

— water-borne robots and flying robots;

— industrial robots, which are covered in ISO 10218;

— robots as medical devices;

— military or public force application robots.

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

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

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

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

2 Normative references

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 Terms and definitions

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

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

[SOURCE: ISO 8373:2012, 2.2]

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

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

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

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

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

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

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

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

3.6
hazard
potential source of harm

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

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

[SOURCE: ISO 12100:2010, 3.12]

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

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

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

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

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

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

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

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

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

[SOURCE: ISO 9000:2005, 3.8.5 modified]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Note 2 to entry: See Figure 1.

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

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

Note 2 to entry: See Figure 1.

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

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

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

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

Note 3 to entry: See Figure 1.

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

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

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

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

Note 4 to entry: See Figure 1.

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

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

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

Note 2 to entry: See Figure 1.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[SOURCE: ISO 8373, 2.17, modified]

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

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

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

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

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

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

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

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

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

— a sensing device;

— controlling/monitoring devices;

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

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

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

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

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

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

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

4 Risk assessment

4.1 General

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

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

4.2 Hazard identification

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

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

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

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

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

e) unintended movement of the personal care robot;

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

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

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

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

4.3 Risk estimation

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

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

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

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

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.

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;