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Robotics — Application of ISO 13482 —

Part 2:
Application guidelines

Robotique — Application de l'ISO 13482 —

Partie 2: Lignes directrices sur l'application

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Foreword

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

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 299, *Robotics*.

A list of all parts in the ISO 23482 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 13482 is the first safety standard developed for the area of service robots. It allows close human-robot interaction, including human-robot contact. Although ISO 13482 follows well-established principles and practices from standards for industrial robots and machines in general, additional guidance can facilitate its rapid and successful adoption by manufacturers and other stakeholders.

This document clarifies which robots fall under the definition of personal care robots and what distinguishes personal care robots from robots in other areas, such as medical robots or industrial robots. This document also provides further guidance on the risk assessment and risk reduction process to be conducted for a personal care robot. It contains examples of risk assessments for different types of personal care robots that can serve as an example for the user of ISO 13482 for their own risk assessment.

Robotics — Application of ISO 13482 —

Part 2:
Application guidelines

1 Scope

This document provides guidance on the use of ISO 13482 and is intended to facilitate the design of personal care robots in conformity with ISO 13482. Additional guidance is provided for users with limited experience of risk assessment and risk reduction. This document provides clarification and guidance on new terms and safety requirements introduced to allow close human-robot interaction and human-robot contact in personal care robot applications, including mobile servant robots, physical assistant robots and person carrier robots. This document considers the application of ISO 13482 to all service robots and includes related examples.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 13482:2014, *Robots and robotic devices — Safety requirements for personal care robots*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8373:2012 and ISO 13482:2014 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
service robot
robot that performs useful tasks for humans or equipment excluding industrial automation applications

[SOURCE: ISO 8373:2012, 2.10, modified — Notes to entry have been deleted.]

3.2
personal care robot
service robot (3.1) that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications

[SOURCE: ISO 13482:2014, 3.13, modified — Notes to entry have been deleted.]

3.3
industrial robot
automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications

[SOURCE: ISO 10218-1:2011, 3.10, modified — Notes to entry have been deleted.]

3.4
mobile servant robot
personal care robot (3.2) that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information

[SOURCE: ISO 13482:2014, 3.14]

3.5
physical assistant robot
personal care robot (3.2) that physically assists a user to perform required tasks by providing supplementation or augmentation of personal capabilities

[SOURCE: ISO 13482:2014, 3.15]

3.6
person carrier robot
personal care robot (3.2) with the purpose of transporting humans to an intended destination

[SOURCE: ISO 13482:2014, 3.16, modified — Notes to entry have been deleted.]

3.7
medical robot
robot intended to be used as MEE or MES

Note 1 to entry: MEE (medical electrical equipment) and MES (medical electrical system) are defined in IEC 60601-1.

[SOURCE: IEC/TR 60601-4-1:2017, 3.20, modified — Note to entry has been added.]

3.8
household robot
actuated mechanism with a degree of autonomy, operating within the household and similar environment, to perform intended tasks

Note 1 to entry: Operating includes travel and/or robot body movement.

[SOURCE: IEC 62849:2016, 3.1]

4 Guidance on the scope of ISO 13482 and gaps or overlaps with other standards

4.1 General

This clause clarifies what robot types and applications are covered by the scope of ISO 13482. It also covers gaps and overlaps with standards for similar products, such as industrial robots, medical robots and light electric vehicles.

4.2 Guidance on the definition of service robots

Service robots include various robot categories performing useful tasks for humans or equipment. Figure 1 illustrates robot categories that are included in the definition of service robot and how they relate to other relevant areas.

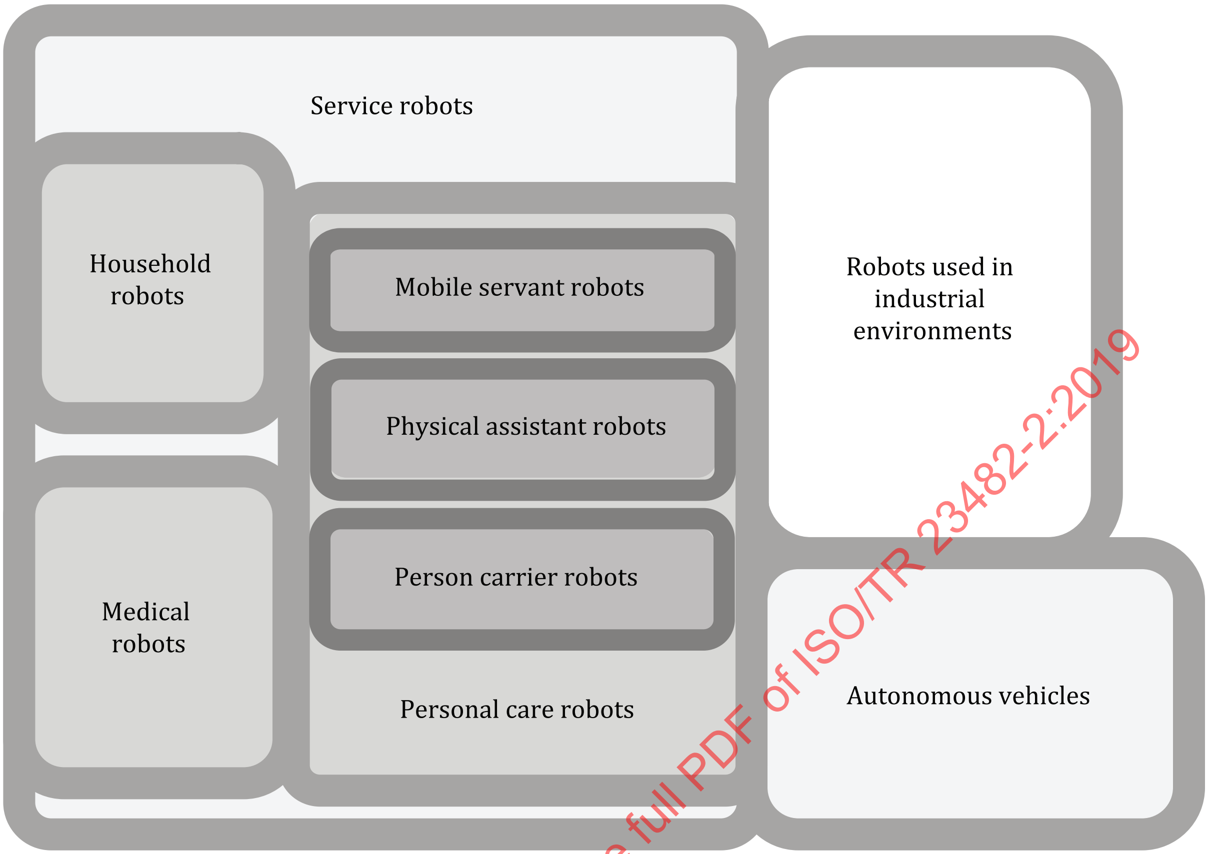


Figure 1 — Categorization of personal care robots and relation with other relevant areas

The term “service robot” contains most robot categories, except industrial robot, as illustrated in Figure 1. As different legal and regulatory requirements apply to different robot categories, one of the first tasks for the manufacturer in commercialization of a robot is to identify the robot category to which it belongs. Robot categories of particular interest to robot manufacturers at the time of publication of ISO 13482 are summarized in Table 1.

Table 1 — Summary of selected robot categories

Robot categories	Purpose	User	Examples
Personal care robot	Improvement of the quality of life of humans (on a non-medical basis)	Lay person (not a patient)	Autonomous mobile robot that takes objects at the request of its user Robot exoskeleton to enhance physical capability of healthy person in non-industrial environment Self-balancing type personal mobility robot
Medical robot	Diagnosis, treatment, or monitoring of a patient; or compensation or alleviation of disease, injury or disability	Patient Medical expert	Robot exoskeleton to compensate disability of affected limbs Surgery robot Self-transfer robot transferring a patient between bed and wheelchair
Household robot	Implementation of housework for humans	Lay person (not a patient)	Autonomous vacuum cleaner Mowing robot
Robot used in industrial environments	Implementation of tasks in industrial automation	Worker	Warehouse mobile robot Welding robot

ISO 10218 was the only International Standard dealing with safety for robots and robot systems prior to the publication of ISO 13482.

4.3 Guidance on the definition of personal care robots

Personal care robots are covered by ISO 13482. They are a subset of service robots that contribute to the quality of life of users through direct interaction.

ISO 13482 is intended to be applied to personal care robots that improve the quality of life of humans regardless of their attribute, age or gender (e.g. children, elderly persons, pregnant women). Since the area of personal care robots is broad, only a small portion thereof was relevant to the existing market at the time of publication of ISO 13482. With the market relevance in mind, ISO 13482 selects the three most commercialized types of personal care robot and specifies safety requirements particularly for these three robot types while allowing its application to any type of personal care robot. The three robot types are mobile servant robot, physical assistant robot and person carrier robot.

The improvement of the quality of life provided by each of the three robot types is as follows.

— Mobile servant robots provide services to their users. These include serving information as well as objects. The role of mobile servant robots can be compared to serving personnel, such as butlers, waiters, secretaries or receptionists.

— Physical assistant robots help the wearer to do a task by physically supporting movements. This includes supporting the user's weight, as well as amplifying the force of muscles.

— Person carrier robots transport users. Such robots can be designed to carry a single person or a small group of persons, at limited speed, normally in pedestrian areas.

Some personal care robots can adopt the attributes of two or more robot types specified in ISO 13482. This kind of hybrid personal care robots includes:

— person carrying exoskeleton (hybrid of physical assistant robot and person carrier robot);

— person carrier robot handling objects and interacting with humans (hybrid of mobile servant robot and person carrier robot).

For such hybrid personal care robots, it is important to identify all relevant safety requirements for the two or more robot types very carefully.

One feature of ISO 13482 compared to ISO 10218 is the physical range of risk of application (see ISO 13482:2014, 6.1.1). Industrial robot applications range from low to high risk, with more applications having high risk. As personal care robots tend to have more direct physical contact with humans than industrial robots, there was a tendency for manufacturers to produce more robots with low risk at the time of publication of ISO 13482. This trend in the personal care robot market is reflected by the intensive coverage of robots with low risk.

4.4 Guidance on the distinction between personal care robots and other robots

There are some known overlaps of scope between ISO 13482 and other standards. Such overlaps allow more than two interpretations of robot category applicable to one robot. To minimize double interpretations, the robot category can be identified based on the intended use of the robot in question. The purposes of the four most market-relevant robot categories are specified in Table 1. The following are examples of identifying robot category based on the purpose of the robot.

— A wearable robot for diagnosis, treatment, or monitoring of a patient, or for compensation or alleviation of diseases, injury or disability, is categorized as a "medical robot" (see IEC 60601-1). The same wearable robot can be categorized as a "physical assistant robot" (ISO 13482:2014, 3.15), if used otherwise, e.g. exoskeleton robot assisting medical worker to transfer a patient.

— A mobile robot for transporting parts for an assembly line can be categorized as a "robot used in industrial environments". The same robot can be categorized as a "mobile servant robot" (ISO 13482:2014, 3.14) if used otherwise, e.g. a mobile robot for fetch and carry tasks in the household.

— A wearable robot assisting a factory worker in installing a door onto an automobile in manufacturing premises, can be categorized as a "robot used in industrial environments". The same robot can be categorized as a "physical assistant robot" if used otherwise, e.g. to minimize factory worker's fatigue when not performing tasks in factory automation.

It is usually in the interests of a robot manufacturer to identify one singular type to which a particular robot belongs. In this way, it is only necessary to fulfil the safety requirements for this type and contradicting requirements from different standards are avoided. When a particular robot can belong to more than one type, the manufacturer chooses the robot type, intended use, conditions for use and limitation for use.

If a robot is intended to be used for multiple purposes, the robot is normally considered to belong to multiple robot types. One such example is an autonomous mobile robot able to serve food and beverages ("mobile servant robot") and also managing and dispensing medication to a patient ("medical robot"). In such a case, both applicable medical device standards and machinery standards should be considered.

NOTE 1 If a robot is designed in a way that software can be altered, it is important that the manufacturer specifies the limits of use and selects applicable safety standards accordingly for the risk assessment process. If the software is altered beyond the specified limits (e.g. using a non-medical robot for a medical task), a new risk assessment is conducted according to ISO 12100 (or another applicable standard) by the party responsible for the alteration.

In the following examples, the boundaries of the personal care robots and the other products need to be clarified:

— a driverless road vehicle can be classified as a person carrier robot if the speed is limited to 20 km/h; ISO 13482 applies;

— a person carrier robot is classified as a road vehicle if it is used on the public roads; regulations for road vehicles apply.

NOTE 2 To determine which standards to apply in case of conflicting requirements, the manufacturer can consult a third party qualified to provide advice until the boundaries are clarified. This can be from organizations accredited according to ISO/IEC 17025.

Reasonably foreseeable misuses are identified in the risk assessment, according to ISO 12100. The robot design can be changed to lessen the likelihood of foreseeable misuses. When these cannot be eliminated, they are used to determine the intended uses and limitations of use of the personal care robot.

5 Concepts in ISO 13482

5.1 General

ISO 13482 addresses safety issues that are distinct compared to medical and industrial robots. The following are some elemental differences between personal care robots and other existing machinery:

- personal care robots are usually mobile and work among humans without being separated by guards;
- interaction between human and robot, including physical contact, is often an essential part of the robot's task;
- personal care robots often have a certain degree of autonomy which enables them to act and decide without human intervention.

5.2 Interaction without guards

Personal care robots are usually designed to operate among humans, sharing their operational space with them. In addition, personal care robots are usually mobile. As a result, protective devices are usually attached to, or can be integrated with, the personal care robot, rather than being installed in the environment. Operating zones and zones safeguarded by protective devices and safety functions are defined relative to the mobile personal robot.

Due to the closer interaction with humans, the protective stop is not considered the only option to achieve a safe state. More flexibility can be reached when the robot adjusts its speed to the distance and the relative speed of obstacles. To guarantee safe interaction, safety functions such as safety-related speed control and obstacle avoidance can be applied. Requirements for the control system performance of such safety functions are provided in ISO 13482:2014, 6.4 and 6.5.

5.3 Intended physical contact

Physical contact with the user is often essential for the task of a personal care robot. This applies especially for physical assistant robots where force is directly applied to parts of the human body, but it is also important that person carrier robots are in permanent contact with their rider. Mobile servant robots establish temporary physical contact, e.g. when objects are handed over.

During robot design and risk assessment, it is important that a manufacturer distinguishes between intended and unintended forms of physical contact. For intended contact, it is important to limit contact forces and impacts to a level that allows interaction with the user without pain or discomfort. A strategy or process is usually developed for controlled engagement and disengagement into/from physical contact. It is important to avoid unintended contact, especially harm from collisions and clamping with high force and impact.

Requirements for the control system performance of a safety-related force control function that can be used to achieve acceptable physical interaction are provided in ISO 13482:2014, 6.6.

5.4 Autonomous functions

Personal care robots are in many cases equipped with autonomous functions. ISO 13482 distinguishes between autonomous and semi-autonomous operation (see ISO 13482:2014, 6.10). During autonomous mode, the frequency of human interaction is very low, e.g. when a mobile servant robot performs household tasks like tidying up or preparing drinks on its own. In semi-autonomous mode, user and robot interact frequently, but the robot is only indirectly controlled by the human.

EXAMPLE When the human controls the general direction of motion of a person carrier robot while the robot performs obstacle avoidance and stability control on its own.

As the level of autonomy in personal care robots is still considerably low and often limited to simple autonomous decisions, ISO 13482 assumes that the manufacturer still carries the full responsibility for autonomous actions of the robot. The robot cannot be responsible itself for its actions, nor is the user responsible for harm originating from autonomous decisions when using the robot as intended. It is important that the manufacturer of a personal care robot judges carefully which actions and decisions can be executed autonomously by such a robot without any unacceptable risk of harm. Further guidance on this issue is provided in ISO 13482:2014, 5.12.

It is expected that the autonomy of personal care robots will increase in the future and will comprise more complex autonomous actions and decisions. The relevant clause of ISO 13482 is therefore likely to be expanded in future revisions.

6 Methodology

6.1 Risk reduction methodology of ISO 13482 in the context of other safety standards

The process of risk assessment and risk reduction is shown in Figure 2, which is adapted from ISO 12100:2010, Figure 1, and has been extended with additional information for users of ISO 13482, including priority of application order of the risk reduction measures.

As shown in Figure 2, as a first step, the limits of the robot are determined, and thereby the environment and the use context or application in which the robot operates. Based on these limits, hazard identification is performed and the risk associated with the identified hazards is estimated. Risk reduction is required if risk evaluation indicates that a risk has not been adequately reduced. It is the manufacturer's responsibility to determine the acceptable risk. Acceptable risk can be understood as the level of risk that is accepted in a given context based on the current values of society.

A risk reduction is performed according to the three-step method illustrated in Figure 2 for any risks which need risk reduction. The first step is to reduce the risk by applying inherently safe design measures. The second step (the reduction of the risk by applying safeguards or complementary protective measures) can only be applied when the first step is not applicable or the necessary risk reduction cannot be achieved by applying the first step. In the same way, the third step is not applicable without performing the first and the second step.

The process of risk reduction is always iterative. After measures have been applied, the residual risk is again assessed to determine if the risk is adequately reduced. These steps are repeated until finally all the remaining risks are adequately reduced.

For hazard identification, the list of significant hazards provided in ISO 13482:2014, Annex A, can be used as a checklist. This list is not exhaustive and does not necessarily cover all hazards of a particular personal care robot: as a supplement, the more general list of hazards provided in ISO 12100:2010, Annex B, can be used to identify less common hazards.

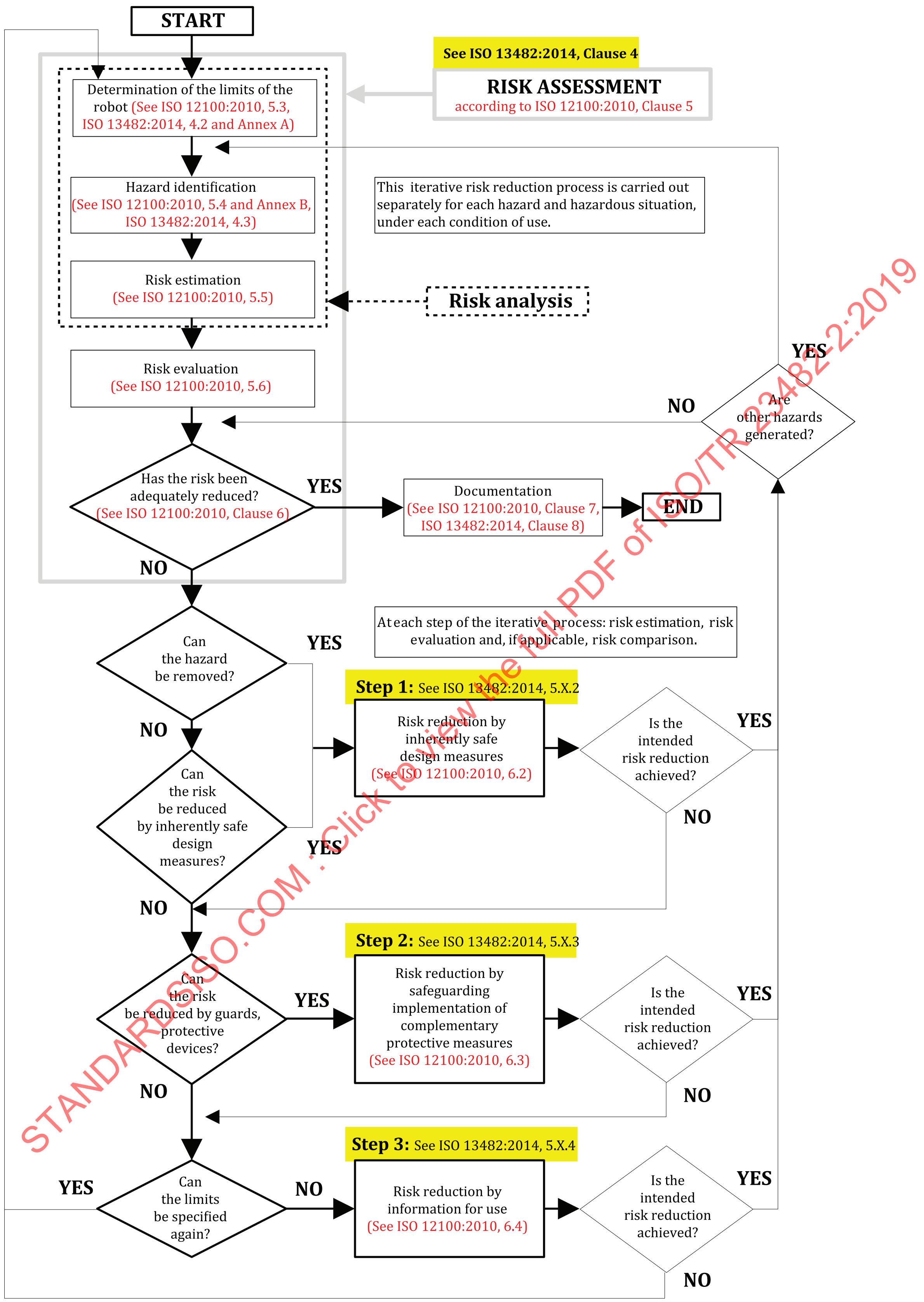


Figure 2 — Schematic representation of risk reduction process with extended information for users of ISO 13482

ISO 13482:2014, Clause 5, is structured in such a way that appropriate measures for the three steps of risk reduction are provided for each particular hazard in subsequent subclauses, as follows:

— 5.X.2 Inherently safe design;

— 5.X.3 Safeguarding and complementary protective measures;

— 5.X.4 Information for use.

This allows the user to take all possible measures for risk reduction into account and choose appropriate solutions according to the priorities defined in ISO 12100.

NOTE 1 Other measures than those mentioned in ISO 13482:2014, 5.X.2 to 5.X.4, can be chosen for risk reduction if they are considered to be appropriate.

When safety functions are implemented for risk reduction using the safety-related part of the control system, ISO 13482:2014, Clause 6, applies, with each safety function being realized with a sufficiently high safety performance level (PL). The definition of PL and categories of control architecture are described in ISO 13849-1. Before applying ISO 13482:2014, Clause 6, users are highly encouraged to familiarize themselves with the principles and methodology described in ISO 13849-1.

NOTE 2 This document uses PL for evaluation of safety related control circuit according to ISO 13849-1. However, safety integrity level (SIL) defined in IEC 62061 can also be applied for the same purpose.

ISO 13482 requires that the required performance level (PLr) for a certain safety function be determined by risk assessment, taking into account expected probability and severity of harm. ISO 13482:2014, Clause 6, contains recommendations for the PL of typical safety functions for typical robot types. However, the recommendations in ISO 13482 only serve as a guideline and are not a substitute for users to determine the PLr of their particular robot. Compared with the recommended PL, the PLr determined by the user can be higher or lower.

— Higher: In this case, the particular personal care robot has risks that are higher than the risks of typical examples of personal care robots illustrated in ISO 13482. The manufacturer needs to fulfil all the requirements of ISO 13849-1 to mitigate these higher risks.

— Lower: In this case, the particular personal care robot can have risks that are lower than the risks of typical examples of personal care robots illustrated in ISO 13482. However, it should be ensured that substantial reasons exist for this outcome of risk estimation. These reasons should be carefully documented in the technical documentation of the robot for later review.

Expected safety-related control functions of personal care robots are used as titles from ISO 13482:2014, 6.2 to 6.11. Each clause shows requirements for the safety-related control system with expected PL.

ISO 13482 subdivides each robot type into a high-risk sub-type and a low-risk sub-type of each example of a robot type. Choosing either sub-type results in different recommendations for the PLr, which are usually based on the choice of a high or low expected severity in the associated risk graph. This differentiation serves as an additional guideline for the user. However, it is not a substitute for performing a risk assessment to determine the PLr for each safety function. In practice, a robot that at first sight seems to correspond to the "low-risk" definition can prove to require safety functions with high PL after careful inspection. The robot sub-type can be changed by implementing inherently safe design measures.

6.2 Approach adopted for the working examples

Clause 7 comprises working examples to provide guidance on the following subjects:

— procedural steps for risk assessment and the generation of a risk assessment table;

— the application of the ISO 12100 risk reduction methodology;

— the application of safety PL for the safety-related control system function according to ISO 13849-1;

— conformity to specific safety requirements in ISO 13482.

Each working example shows how to use ISO 13482 rules to identify the correct sub-type of the robot and then shows the process to identify the required PLs of its safety functions. In particular, the following information is provided.

— A presentation of the general characteristics of the robot that are relevant for the risk assessment, such as system architecture, specifications, operating environment, typical use scenarios including degree of autonomy of specific tasks, and robot sub-type determination (size-related assessment/mass-related assessment/speed-related assessment/force/power-related assessment/etc.).

— Determination of the limits of the personal care robot, including foreseeable misuse. A sample of initial risk estimation for a few selected risks and hazards. The tables have at least one control-function related risk reduction measure. The table consists of hazard, potential consequences, hazardous event, initial risk estimation and evaluation and a link to ISO 13482:2014, Clause 5.

— A selection of inherently safety measures, safeguarding measures for hazards, as well as generation of information for use for the most important risks and hazards addressed in the initial risk assessment table. A risk assessment table after the risk reduction measures has been applied for risks and hazards in the initial risk assessment table. Care should be taken if any measure causes any new hazard. The same procedure is repeated until all the identified risks are adequately reduced.

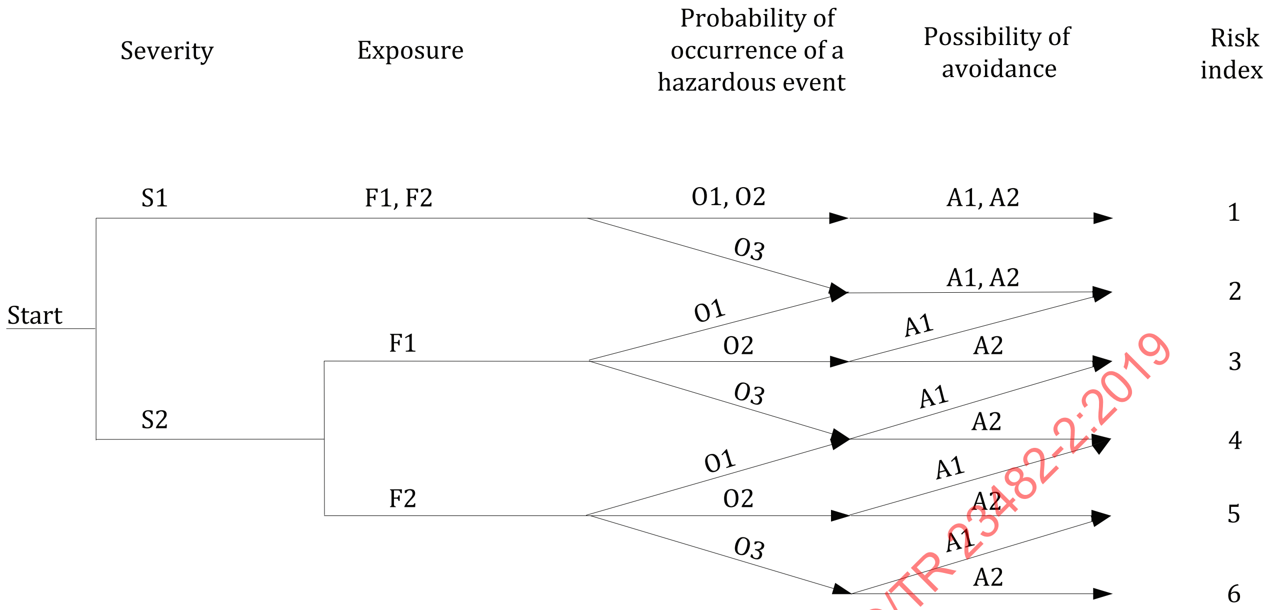
— Identification of safety-related control functions used for protective measures and determination of PLr for identified control functions.

The items listed in ISO 12100:2010, Clauses B.1 to B.4, are the types of hazard, their origin and their potential consequences to be identified before risk estimation/evaluation, and these clauses also provide hazardous situations and hazardous events.

For better readability, the working examples in Clause 7 do not offer detailed information regarding the origins of hazards nor provide hazardous situations. Origins of hazards and hazardous situations can be implicitly read in the column “hazard and hazardous event”, which contains cause and effect resulting in a potential consequence.

The examples in this document are not intended to cover all the risks, but to cover some specific examples. Risk estimation and evaluation in each example relates to Figure 3. Determination of PLr in each example adopts the methodology shown in Figure 4. This document uses separate risk graphs for risk estimation/evaluation and determining the PLr of safety functions in order to present the different steps of risk assessment and risk reduction in a structured and comprehensible way. Since two different risk graphs are used in the overall process, care should be taken to ensure consistency of analysis between the risk estimation driving the need for risk reduction measures and that for determining PLr. Other techniques are available that do not use multiple risk graphs.

EXAMPLE RIA TR R15.306-2016 task-based risk assessment methodology provides an example of mapping the risk index to PLr without using a second risk graph.



Key

S1 slight injury (usually reversible)

S2 serious injury (usually irreversible)

F1 seldom/short duration

F2 frequent/long duration

O1 low (very unlikely)

O2 medium (likely to occur sometime)

O3 frequent (likely to occur frequently)

A1 possible (person can notice and has time to evade)

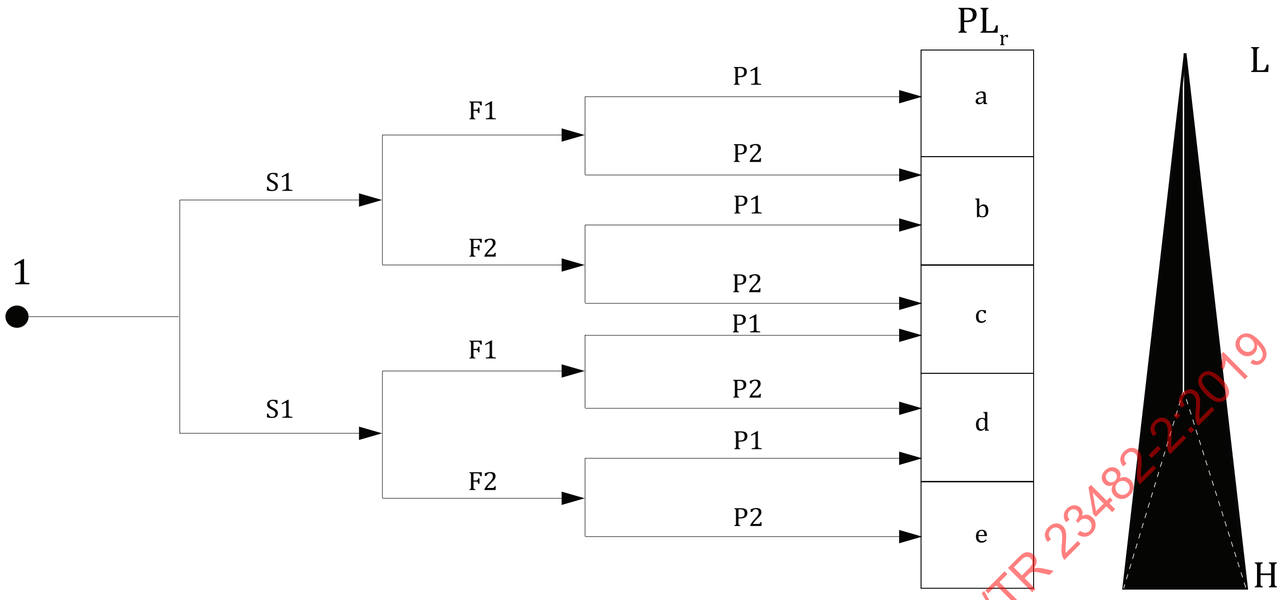
A2 impossible

NOTE 1 This figure is an example to illustrate the procedures to apply ISO 13482. It is reproduced from ISO/TR 14121-2:2012, 6.3.2, which contains more detailed explanation of the alternatives for S, F, O and A.

NOTE 2 A risk index of 1 or 2 corresponds to a low risk, a risk index of 3 or 4 corresponds to a medium risk and a risk index of 5 or 6 corresponds to a high risk. The manufacturer decides up to which risk index a risk is still acceptable, normally with a justification.

NOTE 3 F, O and A together form the “probability of occurrence of harm”.

Figure 3 — Risk estimation and evaluation



NOTE The criterion “F” is defined differently for the two risk graphs, i.e. “F” and “O” of Figure 3 correspond to “F” in Figure 4.

Figure 4 — Determination of PLr for safety function

6.3 Application of wording examples to other robots

The working examples for risk assessment and risk reduction are based on assumptions for a certain robot design and a use scenario. They should be considered to provide guidance for users of ISO 13482 to perform their own risk assessment and risk reduction. Although the examples are intended to be as realistic as possible, it is not possible to apply the results of these examples to any other personal care robots, in particular for the following reasons:

— Some hazards and some risk reduction measures have been omitted to keep the examples short and understandable.

— Different personal care robot designs have different risks, even if they are apparently similar.

— Even identical personal care robots result in different risks and require different risk reduction measures, if they are used in a different environment or by different user groups.

— It is important to verify carefully, by means of calculations and practical tests, the ability of a safeguard or complementary protective measure to reduce a risk adequately.

7 Working examples

7.1 Description policy

Clause 7 shows step-by-step procedures to perform risk assessment and risk reduction for personal care robots specified in ISO 13482. The examples given in Clause 7 represent personal care robots, already commercialized or about to be commercialized at the time of publication. The examples in Clause 7 correspond to the approach described in 6.2.

7.2 Example 1 — Mobile servant robot (high risk)

7.2.1 Overview

This example deals with a mobile servant robot designated to perform fetch-and-carry-tasks in private households in order to support elderly persons.

System architecture:

The robot consists of an omnidirectional mobile base with four wheels. On the base sits a torso with a single arm. The arm is equipped with a 3-finger-gripper. The robot also has a foldable tray on which objects can be placed. The robot is powered by a lithium-ion battery which is located in the mobile base.

Specifications:

The robot is about 1,5 m high and weighs 150 kg. The gripper can lift a maximum load of 2 kg. The robot has a maximum travel speed of 1 m/s. The voltage of the battery is 48 V.

Operating environment:

The mobile servant robot is designated to operate indoors, in home environments with flat ground.

Typical tasks:

The following tasks are foreseen for the mobile servant robot:

— locating and fetching objects from a place inside the home environment (e.g. kitchen, shelf in the living room, side table in the bedroom) upon user command;

— receiving objects from a user and bringing them to an appropriate place (e.g. a dirty cup back to the kitchen; a book back to the bookshelf);

— pouring drinks from bottles and serving them to sitting or standing persons.

Task execution is triggered by verbal user commands, by pressing a button on a remote control (e.g. smart phone app) or by placing or taking an object on/from the robot's tray.

Degree of autonomy:

The mobile servant robot works almost entirely in autonomous mode (according to ISO 13482:2014, 6.10). Having received a command, it moves between rooms and avoids obstacles, it locates, grasps and delivers objects without human intervention.

Robot sub-type determination:

The mobile servant robot is equipped with a manipulator. With a weight of 150 kg and a size of 1,5 m, it is neither small nor light-weight. It is categorized as a high-risk mobile servant robot (Type 1.2 according to ISO 13482:2014, 6.1.2.1).

7.2.2 Risk assessment

7.2.2.1 Determination of the limits of personal care robot

The mobile servant robot is operated by a lay person in a home environment to perform the aforementioned tasks. The home environment is expected to have flat ground (hard floor or carpet). During the iterative process of risk assessment, further limitations have been decided to exclude other hazards and make the risk estimation and risk reduction process easier.

— Conditions for use: no steps and sloped surfaces have an angle below 5°.

— Objects to be handled by the robot are limited to non-hazardous objects. Sharp objects (e.g. knives), very hot objects or burning objects (e.g. hot frying pans, burning candles), heavy objects (more than

1 kg) or hazardous substances such as poisonous liquids (e.g. strong cleaning agents) are restricted from being handled by the robot.

— Adults able to understand the hazards originating from the mobile servant robot are to operate the robot. This excludes not only small children, but also people with impaired mental capacity (e.g. elderly people suffering from dementia). If small children are living in the household the robot are to operate under supervision of an adult.

Foreseeable misuse:

It is anticipated that persons can try to sit on the mobile base, e.g. elderly persons because no chair is available or children in order to ride on the robot. This can damage the mobile base or lead to severe injuries if a child falls off the moving base and is run over.

It is anticipated that a user can use the robot to fetch medicine, to pick up pills or even to pour a small amount of liquid medicine into a glass. This can lead to hazardous situations if the robot brings the wrong medicine or the wrong amount. Furthermore, such task functionality would make the mobile servant robot a medical device which is not intended.

To prevent users from sitting on the robot, all surfaces in question are shaped in a way that sitting is either entirely prevented or at least very uncomfortable. Instructions not to use the robot in one of the ways described above will be provided in the user information.

7.2.2.2 Initial hazard identification and risk estimation

Table 2 lists hazards which have been identified for the mobile servant robot. The list has been compiled by using ISO 13482:2014, Annex A, as a checklist and discussing for each hazard listed in the annex, if a hazard is present. For the sake of brevity, the list is limited to ten items, although it is possible that there are other hazards to be addressed. In addition, Table 2 shows an estimation of the risk originating from these hazards based on the risk graph in Figure 3.

Table 2 — Risk evaluation before applying risk reduction measures

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
1	Electrical	Contact of a person with live battery terminals	Electric shock, discomfort, burn	**S1:** 48 V cannot cause serious harm. **F2:** Robot is frequently touched and terminals can be accidentally accessed. **O3:** Mistake by a lay person can be expected. **A2:** Live parts cannot be recognized before touching. **R: 2**	Acceptable in principle, but marked for further risk reduction, as the probability of occurrence of harm is high and state of the art solutions for this problem are available.	5.2
2	Mechanical	Dropped loads (from gripper) in case of power failure	Crushing, other hazards	**S1:** Only non-hazardous objects may be carried. **F1:** Power failure happens infrequently. **O3:** Loads will always drop from gripper in case of power failure. **A2:** Falling happens unexpectedly. **R: 2**	**Acceptable**, but marked for further risk reduction, as state-of-the-art solutions for this problem are available.	5.3.3
3	Mechanical/ ergonomic	Robot is not noticed when operating in the dark and it frightens the user	Collisions, elderly people stumbling and falling	**S2:** An elderly person who falls can fracture a bone. **F2:** Robot can operate regularly in the dark. **O1:** Frightening a person with severe consequences occurs very seldom. **A2:** The robot is not noticeable. **R: 4**	**Not acceptable**, as severity and probability of occurrence of harm are both high.	5.14
4	Electrical	Water being spilled on the robot, e.g. from served drinks	Electric shock, short circuit causing functional failures (fire and smoke are not considered here)	**S1:** 48 V cannot cause serious harm. **F1:** Spilling happens seldom. **O2:** Spilling will seldom have such consequences. **A2:** Live parts cannot be recognized before touching. **R: 1**	**Acceptable**, as the product of severity and probability of occurrence of harm is low.	5.15

Table 2 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
5	Mechanical	Robot falls over when loads are too heavy or in case of extreme travel manoeuvres	Crushing of a person	**S2:** Severe injury, e.g. fractures are likely. **F1:** Overload or extreme travel manoeuvres are seldom. **O1:** Centre of gravity is near ground due to the heavy battery. **A2:** Falling can happen too quickly to evade. **R: 2**	**Acceptable**, as the probability of occurrence of harm is low and the mechanical stability has been sufficiently addressed in the mechanical design.	5.10.2 5.10.3
6	Mechanical	Load is dropped (from tray) when the robot stops abruptly	Impact, cutting injuries from shards	**S1:** Limited severity as handling of dangerous and heavy objects is not allowed. **F2:** High exposure as stop happens often when a user steps in front of the robot. **O3:** Loads almost always drop when stopping abruptly. **A2:** Falling can happen too quickly to evade. **R: 2**	Acceptable in principle, but marked for further risk reduction, as the probability of occurrence of harm is high and state of the art solutions for this problem are available.	5.10.4
7	Mechanical	Collision with an adult including elderly persons	Impact and crushing injuries	**S2:** Robot is heavy enough to cause non-reversible injuries. **F2:** Robot operates permanently in the vicinity of humans. **O2:** Sensing and obstacle avoidance usually prevent collisions. **A2:** Especially elderly persons cannot evade. **R: 5**	**Not acceptable**, as severity and probability of occurrence of harm are both high.	5.10.8

Table 2 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation **S: Severity of harm** **F: Frequency of exposure** **O: Probability of occurrence** **A: Possibility to evade** **R: Risk index**	Risk evaluation	Clause of ISO 13482: 2014
8	Mechanical	Collision with a small child	Impact and crushing injuries	**S2:** Robot is heavy enough to cause non-reversible injuries. **F2:** Robot operates permanently in the vicinity of humans. **O3:** Sensing and obstacle avoidance can have problems detecting small children. **A2:** Small children cannot evade. **R: 6**	**Not acceptable**, as severity and probability of occurrence of harm are both high.	5.10.8
9	Mechanical	Collision with a pet	Impact and crushing injuries, pet can be killed.	**S2:** Pet can be killed **F2:** Robot operates permanently in the vicinity of pets **O3:** Sensing and obstacle avoidance can have problems detecting small pets. **A1:** Most pets react very quickly. **R: 5**	**Not acceptable**, as severity and probability of occurrence of harm are both high.	5.10.8
10	Mechanical, thermal, chemical, ergonomic	Grasping and bringing wrong objects due to incorrect identification of objects	Scalding, if hot liquids are brought unexpectedly; Poisoning, if poisonous liquids are served; Cutting, if sharp objects are brought. Secondary hazards if such objects are damaged or dropped.	**S2:** Dangerous objects can cause serious injury. **F1:** Dangerous objects are only handled in case of misuse. **O3:** Experience shows that the object identification in question always has uncertainties. **A1:** In most cases detected by the user. **R: 3**	**Acceptable**, if a warning against misuse is provided including guidance how to structure the environment to minimize misuse.	5.12

For the identified hazards, additional information can be found in ISO 13482:2014, Clause 5.

EXAMPLE 1 For the example of dropped loads (#2 and #6), ISO 13482:2014, 5.10.4.1, contains the following requirements.

"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."

Consequently, items #2 and #6 of the risk assessment are revisited in order to consider actions required after a load has been dropped and to determine the risk of loads being dropped in case of emergency stops.

EXAMPLE 2 For the hazard of a lack of awareness of the robot (risk assessment #3), ISO 13482:2014, 5.14.1, contains the following requirements:

"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."

For risk reduction, the emission of noticeable sound seems to be the preferred measure to reduce risks for lack of awareness.

7.2.2.3 Risk reduction measures

During risk assessment, hazards are identified which lead to a risk that is not acceptable or should be reduced. Table 3 shows for three selected hazards which measures are applied to reduce the risk.

Table 3 — Risk reduction measures for three selected hazards

#	Hazard and hazardous event	Potential consequence	Inherently safe design measure	Safeguard or complementary protective measure	Information for use
3	Robot is not noticed when operating in the dark	Frightening the user, collisions, elderly people stumbling and falling	The noise of motors and gearboxes is noticeable but not very loud. As home environments are usually quiet during the night, it is assumed that the sound is noticeable in all situations. A further increase of the sound level would disturb the user and is not possible.	The noticeability of the robot is increased by adding LED light to its outer hull which are integrated in the visual design of the robot. The robot can so be easily seen when it operates in a dark room (see ISO 13482:2014, 5.14.2 and 5.14.3).	Instruction to check functionality of lights on every start-up and to repair non-functioning lights.
6	Load is dropped when the robot stops abruptly	Impact, cutting injuries from shards	The frame of the tray is raised to prevent objects sliding off the tray. This design also holds back spilled fluid. In addition, the tray is coated with a high friction rubber (see ISO 13482:2014, 5.10.4.2).		Additional advice is included in the user manual on which objects can be problematic when carried and should be avoided. Advice is included in the user manual to remove spilled liquids before the robot can resume operation.

Table 3 *(continued)*

#	Hazard and hazardous event	Potential consequence	Inherently safe design measure	Safeguard or complementary protective measure	Information for use
7, 8, 9	Collision with a human including elderly persons, collision with small children or collision with a pet	Impact and crushing injuries	The drive motors and gearbox of the mobile base are chosen so that they do not allow a travel speed of more than 1 m/s. This reduces the overall kinetic energy of the robot (see ISO 13482:2014, 5.10.8.2). The manipulator is chosen so that it does not have more power than the required force to lift the maximum load of 1 kg (see ISO 13482:2014, 5.10.8.2). Overall, the expected severity of harm can be reduced by these measures. As the kinetic energy is lowered, stopping distances of the robot components can be shortened significantly.	The robot is equipped with 3D-sensors for environment surveillance and collision-free path planning. Nevertheless, these functions are realized in potential unsafe software and cannot reach a sufficient PL for risk reduction. To avoid collisions, the mobile base is equipped with laser scanners (ESPE) to detect the presence of persons around the robot (see ISO 13482:2014, 5.10.8.3). Detection sensitivity of the laser scanners are set to the appropriate level so that also body parts with a diameter of 30 mm are detected. This allows detecting at arms and hands of small children as well as many pets.	The risk and applied safeguarding measures are described in the user manual to raise awareness for the hazards related to collisions. Users are advised to stay away from moving parts of the robot. Users are informed of the risk that small pets are not recognized properly by the robot. It is recommended to not use the robot when small animals such as rodents are present.

Table 3 *(continued)*

#	Hazard and hazardous event	Potential consequence	Inherently safe design measure	Safeguard or complementary protective measure	Information for use
				The height of the laser scanners over the ground is lowered, so that children and pets lying on the floor can be detected. A laser scanner close to the ground cannot detect lying persons or sitting persons whose legs do not touch the ground. The manipulator and parts of the robot torso are equipped with a tactile hull (PSPE) which stops the robot motion in case of collision (see ISO 13482:2014, 5.10.8.3). In experimental tests, it is verified that the thickness of the tactile hull is sufficient to prevent harm from excessive impact forces.	

7.2.2.4 Final risk assessment and residual risk

After all risk reduction measures have been applied, a final risk assessment is performed to determine if risk reduction has been successful and to determine the residual risk. Table 4 shows only the hazards selected in 7.2.2.3.

Table 4 — Final risk assessment

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
3	Mechanical/ ergonomic	Robot is not noticed when operating in the dark	The harm of frightening the user, collisions, elderly people stumbling and falling has been eliminated	**S2:** An elderly person who falls can fracture a bone. **F2:** Robot can operate regularly at night. **O1:** The robot is noticeable and cannot frighten anyone. **A1:** The robot is noticeable. **R: 3**	**Acceptable**, as the probability of occurrence of harm has been limited to a low level.	5.14
6	Mechanical	Load is dropped (from tray) when the robot stops abruptly	Impact, cutting injuries from shards	**S1:** Limited severity as handling of dangerous and heavy objects is not allowed. **F2:** High exposure as stop happens often when a user steps in front of the robot. **O2:** The possibility of an object still being dropped is lowered. **A2:** Falling can happen too quickly to evade. **R: 1**	**Acceptable**, as state-of-the-art measures to limit the probability of occurrence of harm have been implemented.	5.10.4
7	Mechanical	Collision with a human including elderly persons	Impact and crushing injuries	**S2:** Robot is heavy enough to cause non-reversible injuries. **F2:** Robot operates permanently in the vicinity of humans. **O1:** Collisions are effectively prevented by safeguards. **A2:** Especially elderly persons cannot evade. **R: 4**	**Acceptable**, as the safeguards have sufficient performance and effectively limit the probability of occurrence of harm.	5.10.8

Table 4 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
8	Mechanical	Collision with a small child	Impact and crushing injuries	**S2:** Robot is heavy enough to cause non-reversible injuries. **F2:** Robot operates permanently in the vicinity of humans. **O1:** Collisions with children are effectively prevented by altering the position and increasing the sensitivity of the safeguards. **A2:** Small children cannot evade. **R: 4**	**Acceptable**, as the safeguards have sufficient performance and effectively limit the probability of occurrence of harm.	5.10.8
9	Mechanical	Collision with a pet	Impact and crushing injuries, pet can be killed. Mental discomfort for the owner of the pet	**S2:** Pet can be killed. **F2:** Robot operates permanently in the vicinity of pets. **O2:** Collisions with larger pets are prevented altering the position and increasing the sensitivity of the safeguards. Small pets can still be killed but users are instructed to keep pets away from the robot. **A1:** Most pets react very quickly. **R: 4**	**Acceptable**, as the probability of occurrence of harm is effectively reduced for most pets that are usually moving freely in home environments and under the condition that noticeable warnings are provided not to let small pets be in the vicinity of the robot.	5.10.8

7.2.3 Safety-related control system

In the risk reduction process, two safeguards are implemented that are part of the safety-related control system. Both the use of laser scanners and the use of a tactile skin are protective devices for avoidance of hazardous collision. If obstacles are detected a protective stop is issued. The mobile servant robot is furthermore equipped with emergency stop buttons on the outer hull. ISO 13482 lists for all safety functions a recommended PL of d, according to ISO 13482:2014, Table 1, Type 1.2. In Table 5, the required control system performance is verified according to the risk graph in ISO 13849-1.

Table 5 — Safety function and assigned PL

#	Safety function	Recommended PL according ISO 13482:2014, Table 1	PL according to ISO 13849-1:2015 S: Severity of injury F: Frequency and/or exposure to hazard P: Possibility of avoiding hazard or limiting harm	Clause of ISO 13482:2014
I	Emergency stop	d	**S2:** Collisions can cause severe injury. **F1:** Emergency stop is used infrequently. **P2:** As the emergency already happened, evasion is hardly possible. **PLr: d**	6.2.2.2
III	Avoidance of hazardous collision (base and torso/ laser scanner)	d	**S2:** Collisions with base and torso can cause severe injury. **F1:** Sensing and path planning usually prevent collisions so that the safeguard is activated infrequent. **P2**: Robot parts can move too fast to be avoided. **PLr: d**	6.5.2.1
IV	Avoidance of hazardous collision (manipulator and gripper/tactile skin)	d	**S2:** Collisions with manipulator and gripper can cause severe injury. **F1:** Sensing and path planning usually prevent collisions so that the safeguard is activated seldom. **P2:** Robot parts can move too fast to be avoided. **PLr: d**	6.5.2.2

Both emergency stop and protective stop can be realized by removing drive power (stop category 0 according to IEC 60204-1). A protective stop is permitted to be a stop category 2 (according to IEC 60204-1) if risks are safely controlled). However, both functions can be handled separately in the control system as the protective stop can be permitted to reset itself automatically when the obstacle is not visible any more. For emergency stop only a manual reset is allowed (see ISO 13482:2014, 6.2.2.1).

7.3 Example 2 — Mobile servant robot (low risk)

7.3.1 Overview

This example deals with a robot solution for entertainment tasks and provision of information in elderly care homes, homes for children with mental disabilities and similar facilities. The robot can play different games with a group of people. It offers to play music and to sing together for amusement. Users can furthermore ask the robot for information, such as the starting time and location of scheduled events in the facility.

System architecture:

The robot consists of an omnidirectional mobile base with three wheels. The robot has two arms with each of three axes which are not suitable for manipulation but are used to interact with the human (e.g. shaking hands) and express robot gestures. It furthermore has a display-type head with two axes to represent emotions. The robot is powered by a lithium-ion battery which is charged through the line. The robot can be controlled and operated by an external device (e.g. smart phone or tablet).

Specifications:

The dimension of the robot is 480 mm (width) × 520 mm (length) × 1 148 mm (height) and the weight is about 21 kg. The maximum speed is 0,6 m/sec. The maximum running noise of the robot is about 60 dB. The touch sensors in the end of the arms are used to interact with human. The robot has a laser scanner, a 3D camera, a CCD camera, a gyro sensor and ultrasonic sensors to navigate and avoid collisions with objects in the environment.

Operating environment:

The robot is designated to operate indoors, in homes, hospitals, elderly care centres, or classroom environments with flat ground.

Typical tasks:

The following tasks are performed by the personal care robot:

— playing games with a group of users that involve speaking, making gestures, moving around in a room and recognizing people and objects;

— playing music and singing with a group of people;

— answering questions and providing information;

— interacting with users using the smart phone or interaction via speech;

— emotional interaction using arms, wheels, LED, 3D graphic avatar and sound;

— making a gesture with arms, then the user follows the robot motion.

Task execution can be triggered by the remote-control device (e.g. smart phone).

Degree of autonomy:

The mobile servant robot works almost entirely in autonomous mode (according to ISO 13482:2014, 6.10). Having received a command, it moves in indoors and avoids obstacles.

Robot sub-type determination:

The robot is equipped with arms, but they are only used to make gestures. Drive power and mass of the arms is sufficiently low, so that no additional risk arises from their movement. With a size of 800 mm height, 400 mm width × 450 mm length and a weight of 21 kg and 0,6 m/s, it is sufficiently small and light-weight and low speed. It is categorized as a low-risk mobile servant robot (Type 1.1 according to ISO 13482:2014, 6.1.2.1).

Although the robot is used by elderly persons (possibly suffering from dementia), persons with disabilities, or children, the robot is not considered as a medical device, because it is not intended for diagnosis, treatment or monitoring of a patient, compensation or alleviation of a disease, injury or disability.

7.3.2 Risk assessment

7.3.2.1 Determination of the limits of personal care robot

The operating environment is to have flat ground (hard floor or carpet). During the iterative process of risk assessment, further limitations have been decided to exclude other hazards and make the risk estimation and risk reduction process easier.

— Conditions for use: no steps and sloped surfaces have an angle below 5°.

— The user is to be instructed to twist or bend the arms with an intentional force.

— Only adults who are mentally able to fully understand the hazards originating from the mobile servant robot are to set up and supervise the robot. However, the robot can interact with small children and elderly people suffering from dementia, for example. The robot is to be used under supervision of a mentally able adult.

Foreseeable misuse:

It is anticipated that persons can try to sit on the robot or to put load on the robot, e.g. elderly persons because no chair is available or children in order to ride on the robot. This can damage the robot or lead to injuries if a child falls off.

When the robot is charging, if the user moves the head, arms or body of robot, it can lead to hazardous situations.

It is further anticipated that the robot can be misused to provide information regarding medication or medical treatment. This would make the robot a medical device which is not intended. The robot should not be used for diagnosis, treatment or monitoring of a patient, compensation or alleviation of a disease, injury or disability.

It is also anticipated that the user can place the robot on a table or a platform to allow a group of users a better view on the robot. To avoid the harm from the robot falling down, the robot cannot be used in such a way. As stated above the robot can only be operated on flat ground without any steps.

7.3.2.2 Initial hazard identification and risk estimation

Table 6 lists hazards which have been identified for the mobile servant robot. The list has been compiled by using ISO 13482:2014, Annex A, as a checklist and discussing for each hazard listed in the annex, if a hazard is present. For the sake of brevity, the list is limited to seven items, although it is possible that there are other hazards to be addressed. In addition, Table 6 shows an estimation of the risk originating from these hazards based on the risk graph in Figure 3.

Table 6 — Risk evaluation before applying risk reduction measures

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
1	Electrical	Battery short-circuit	Fire, discharge of hazardous fumes or substances	**S2**: Battery failure does not cause serious injury. However, if the short circuit causes a fire, the injury can be high. **F2**: The robot can be charged while operating close to humans. **O1**: Equipped lithium-ion battery has embedded safety circuit and is covered with flame-resistance case. (The battery is compliant to IEC 62133-1). **A2**: Failure cannot be detected in advance. **R4**	**Acceptable**, the current state of art does not provide better solutions.	5.2
2	Mechanical	Failure to detect safety-related objects in workspace	Impact and crushing of a person, blunt force injuries	**S1**: The robot is light and moves at low speed, harm causes no serious injury. **F2**: Robot permanently operates near humans and interacts with them. **O3**: Sensing function has no functional safety rating. Occurrence can be medium or even high. **A2**: The elderly person is not able to avoid without agility. **R2**	**Acceptable, but marked for further risk reduction**, as the probability of occurrence of harm is high and state of the art solutions for this problem are available.	5.10.8

Table 6 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
3	Noise	Harmful level of acoustic noise from gearbox and motors which been identified to emit a high-frequency sound during operation	Stress, discomfort, pain	**S1**: If the elderly person is wearing a hearing aid, noise causes stress. **F2**: Noise occurs continuously during operation of the robot. **O3**: This hazardous event occurs frequently during the operation of robot. **A1**: It can be avoided. **R2**	**Acceptable**, but marked for further risk reduction.	5.7.1
4	Mechanical	Travel instability during basic travel pattern causing the robot to fall over	Collision, impact, crushing injuries	**S1**: The robot is lightweight so it does not lead to severe injury. **F2**: User is continuously exposed while playing with the robot. **O2**: Robot is inherently stable but can become unstable in some extreme movement patterns. **A2**: The elderly person or children are not able to avoid without agility. **R1**	**Acceptable, but marked for further risk reduction**, as the probability of occurrence of harm is high and state of the art solutions (e.g. reducing the maximum speed) for this problem are available.	5.10.3

Table 6 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
5	Mechanical	Navigation errors causing the robot to stop somewhere in the building, possibly blocking a path (door, elevator, etc.)	A person cannot evade from a room. In an emergency situation, care personnel cannot reach a person	**S2**: In critical situations blocking of a path can lead to severe injuries. **F1**: Blocking a critical path in a critical situation happens seldom. **O2**: Navigation errors can happen from time to time. **A1**: The robot can be moved manually. **R2**	**Acceptable**, because the robot can be picked up and moved manually.	5.16
6	Mechanical	Hazardous physical contact with robot arm during human-robot interaction	Impact, collision, blunt force injuries	**S2**: Motion of robot arms can cause head injury. **F2**: Performing games associated with gesture is the normal use case. **O3**: A collision is likely to happen as there is no safeguard. **A2**: A person can be surprised by the movement and has no time to evade. **R6**	**Not acceptable**, as severity and probability of occurrence of harm are both high.	5.10.9
7	Mechanical	Falling off a table or elevated platform	Crushing injuries	**S2**: Severe injury possible when falling on a person. **F2**: Robot continuously operates near humans. **O3**: Likely occur as the robot has no sensors for detecting steps. **A2**: An elderly person can hardly evade. **R4**	**Not acceptable**, Instructions will be included in the manual to not place the robot on elevated platforms or tables.	5.10.3

7.3.2.3 Risk reduction measures

During risk assessment, hazards are identified which lead to a risk that is not acceptable or should be reduced. Table 7 shows for three selected hazards which measures are applied to reduce the risk.

Table 7 — Risk reduction measures for three selected hazards

#	Hazard and hazardous event	Potential consequence	Inherently safe design measure	Safeguard or complementary protective measure	Information for use
2	Failure to detect safety-related objects in workspace	Impact and Crushing of a person, Blunt force injuries	Maximum travel speed of robot is inherently limited to 0,6 m/sec by selection of drive units (see ISO 13482:2014, 5.10.8.2).	The robot is equipped with a protective device (e.g. safety laser scanner) for obstacle detection. (see ISO 13482:2014, 5.10.8.3)	Description of the applied protective measures, operation limits and the hazard related with collision.
3	Harmful levels of acoustic noise	Stress, discomfort, pain	Noise reduced below 60 dB by using low-noise drives and gearboxes and possibly some isolation	Noise insulation cover	Notice to supervisors that people with hearing aids can experience stress.
6	Hazardous physical contact with robot arm during human-robot interaction	Impact, collision, blunt force injuries	A breakaway clutch mechanism is applied at the robot's elbow to mitigate the impact occurred in abrupt movement.	Limiting the robot's workspace to prevent the arms from moving up to the level of a standing person's head (see 6.3). (This does not reduce the risk of collision with sitting persons or small children, for example.)	Information for the user to stay away from moving parts of the robot and provision of guidance to minimize contact with the head area.

7.3.2.4 Final risk assessment and residual risk

After all risk reduction measures have been applied, a final risk assessment is performed to determine if risk reduction has been successful and to determine the residual risk. Table 8 shows only the hazards selected in 7.3.2.3.

Table 8 — Final risk assessment

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
2	Mechanical	Failure to detect safety-related objects in workspace	Impact and Crushing of a person, Blunt force injuries	**S1:** The robot is light and moves at low speed, physical contact causes no serious injury. **F2:** Robot is intended to operate near humans. **O1:** Reduced travel speed and use a protective device reduced the risk of occurrence to near zero. **A2:** The elderly person is not able to avoid without agility. **R1**	**Acceptable**, as state-of-the-art measures to limit the probability of occurrence of harm have been implemented.	5.10.8
3	Electrical/ ergonomic	Harmful levels of acoustic noise	Stress, discomfort, pain	**S1:** If the elderly person is wearing a hearing aid, noise causes stress. **F2:** Noise occurs continuously during the operation of robot. **O1:** Noise is effectively reduced by the additional measures. **A1:** It can be avoided. **R1**	**Acceptable**, as the probability of occurrence of harm has been decreased.	5.7.1
6	Mechanical	Hazardous physical contact with the robot arm during human-robot interaction	Impact, collision, blunt force injuries	**S1:** Clutch mechanism and the workspace limits reduce the possible harm. **F2:** Performing games associated with gesture is the normal use case. **O3:** A collision is likely to happen as there is no safeguard. **A2:** A person can be surprised by the movement and has no time to evade. **R2**	**Acceptable**, as the workspace limit and the clutch mechanism limit the severity.	5.10.9

7.3.3 Safety-related control system

In the risk reduction process, safeguards that are part of the control systems are implemented. The safety laser scanner is a measure for avoidance of hazardous collision. In Table 9, the required control system performance is verified according to the risk graph in ISO 13849-1.

Table 9 — Safety function and assigned PL

#	Safety function	Recommended PL according ISO 13482:2014, Table 1	PL according to ISO 13849-1:2015 S: Severity of injury F: Frequency and/or exposure to hazard P: Possibility of avoiding hazard or limiting harm	Clause of ISO 13482:2014
I	Avoidance of hazardous collision (mobile platform)	c	**S1:** Collisions with low speed cannot cause severe injury. **F2:** The user is exposed throughout the whole operation time. **P2:** The elderly person or children are not able to avoid as to the lack of agility. **PLr: c**	6.5.2.1
II	Limits to the robot workspace (preventing lifting the arms to high)	c	**S1:** Collisions with arms cannot cause severe injury after the mechanical clutch has been applied. **F2:** Performing games associated with gesture is the normal use case. **P2:** A person can be surprised by the movement and has no time to evade. **PLr: c**	6.3
III	emergency stop	d	**S2:** Some hazards (e.g. falling) can cause severe injury. **F1:** Emergency stop is used infrequently. **P2:** As the emergency already happened, evasion is hardly possible. **PLr: d**	6.2.2.2
IV	Protective stop	b	**S1:** All safeguarded hazards have low severity. **F2:** Robot is often in direct interaction with the user and no other sensors for preventing arm collisions exist. **P2:** Elderly persons can hardly evade. **PLr: c**	

7.4 Example 3 — Restraint type physical assistant robot

7.4.1 Overview

This example deals with a restraint type physical assistant robot that assists upper and lower limbs of a user during walking on a flat floor, walking up and down a step-stool, grasping objects from high shelves, and lifting objects.

System architecture:

The robot is a lithium-ion-secondary-battery-powered exoskeleton equipped with eight motors for shoulders, elbows, hip joints, and knee joints to assist the motion of user's upper and lower limbs. Attachments covering chest, shoulders and waist, as well as cuffs around upper arms, forearms, thighs and shins are provided.

Specifications:

Rated torque of the motors for shoulders and elbows is 10 Nm while that for hip joints and knee joints is 20 Nm (rated torques well below the capability of the intended user population). The size of the exoskeleton is adjustable according to the user. Assist modes, for executing different motion tasks, can be selected by manual switch.

Operating environment:

The robot is designed to operate in an indoor environment with ambient temperature between 0 °C and +30 °C including flat ground and a step-stool.

Typical tasks:

The following motion tasks are foreseen for the robot and require different assist modes:

— assisting a user walking on a flat floor;

— assisting a user climbing up a step-stool;

— assisting a user to reach objects, and to pick them up from shelves;

— assisting a user descending from the step-stool.

The user switches operation modes manually.

Degree of autonomy:

The robot in this working example operates in semi-autonomous mode (according to ISO 13482:2014, 6.10). Degree of autonomy for all relevant tasks is low.

Robot subtype determination:

The robot is categorized as Type 2.1 (low powered physical assistant robot) because the maximum assistive force would not injure the user nor block the balancing capability of the user. Practical tests have been conducted during the design process to verify that the balancing capability of the user is not affected if the exoskeleton is switched off during the climbing process. The mass is lightweight enough to be lifted and moved by the user. The moving speed of the robot joints is slow enough for reaction by the user.

NOTE A physical assistant robot is considered low powered if the user can overpower the robot. See ISO 13482:2014, 6.1.2.

7.4.2 Risk assessment

7.4.2.1 Determination of the limits of personal care robot

The following limits are assumed for the robot in this example:

— the user provides all motion intentions and the robot provides assistance;

— users of the robot are persons, who do not have any physical disabilities and who have received instructions on use and safety functions, as specified by the manufacturer;

— the user is at least 14 years old;

— the user's weight does not exceed 100 kg.

Foreseeable misuse:

The following misuse can be anticipated:

— using the robot outdoors;

— touching electrically live parts with a wet hand;

— using the robot in an ambient temperature exceeding +30 °C;

— wearing an unsuitable size of robot;

— using the robot untied or tied incorrectly;

— using the robot in an unexpected area or space, e.g. a narrow space, or an environment where dust or condensation is expected.

The following are examples of two measures to prevent misuse that can be decided by the manufacturer:

— the robot will only be sold by shops with trained personnel who can help to determine the correct size of the exoskeleton and can show correct tying and untying once;

— the robot will only be sold together with a training that covers handling instructions.

7.4.2.2 Initial hazard identification and risk estimation

Table 10 lists hazards which have been identified for the restraint-type physical assistant robot. The list has been compiled by using ISO 13482:2014, Annex A, as a checklist and discussing for each hazard listed in the annex, if a hazard is present. For the sake of brevity, the list is limited to ten items, although it is possible that there are other hazards to be addressed. In addition, Table 10 shows an estimation of the risk originating from these hazards based on the risk graph in Figure 3.

Table 10 — Risk evaluation before applying risk reduction measures

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation **S: Severity of harm** **F: Frequency of exposure** **O: Probability of occurrence** **A: Possibility to evade** **R: Risk index**	Risk evaluation	Clause of ISO 13482: 2014
1	Mechanical	Unintended start-up	Leg or arm injury	**S1:** The user can overpower the robot and only minor injury is expected. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O2:** The hazardous event can occur at medium frequency. **A1:** User can overpower the robot at any time. **R1**	**Acceptable**, as severity is low and the user can overpower the hazard.	5.4
2	Mechanical	Loss of stability and falling from a step-stool due to unexpected actuator forces	Head injury	**S2:** Fall from step-stool can lead to serious head injury. **F2:** User wears the exoskeleton continuously. **O1:** For this low-power exoskeleton, unexpected actuator forces do not affect balancing capability. **A1:** User can overpower the robot at any time. **R3**	**Acceptable**, as the probability of occurrence of harm is low and the user can detect the hazard and react to counter it.	5.10.2
3	Mechanical	Loss of balance and tripping due to unexpected actuator forces	Head injury	**S2:** Fall from upright position can lead to serious head injury. **F2:** User is wearing the exoskeleton continuously. **O1:** It is tested that unexpected actor forces usually do not affect balancing capability. **A1:** User can overpower the robot at any time. **R3**	**Acceptable**, as the probability of occurrence of harm is low and the user can detect the hazard and react to counter it.	5.10.2

Table 10 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
4	Mechanical	Application of assistive torque in an unintended direction, not affecting balance of user	Leg injury, arm injury	**S1:** The user over powers the robot and only minor injury is expected. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O2:** The hazardous event can occur at medium frequency. **A1:** User can overpower the robot at any time. **R1**	**Acceptable**, as severity is low and the user can detect the hazard and react to counter it.	5.10.2
5	Mechanical	Collapse due to loss of assistive torque	Leg injury, arm injury, back injury	**S1:** Friction of motors mitigates the sudden loss of assistive force and slows down possible collapse. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O2:** The hazardous event can occur at medium frequency. **A1:** The friction of motors reduces the speed of change of assistive force, and the user can react to avoid the harm. **R1**	**Acceptable**, as severity is low and the user can detect the hazard and react to counter it.	5.3.3
6	Electrical	Fire hazard of batteries	Burn	**S2:** Serious burn is possible. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O2:** Secondary battery of seldom experiences fire hazard. **A2:** The robot cannot be taken off quickly enough to escape the fire. **R5**	**Not acceptable**, as severity and probability of occurrence of harm are high.	5.3

Table 10 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation **S: Severity of harm** **F: Frequency of exposure** **O: Probability of occurrence** **A: Possibility to evade** **R: Risk index**	Risk evaluation	Clause of ISO 13482:2014
7	Thermal	Maintenance person touching a high temperature part inside the robot during maintenance	Burn	**S1:** High temperature parts of this robot can cause only minor burn. **F2:** The maintenance person is exposed to this hazard whenever a recently used exoskeleton is opened. **O3:** Normal use leads to high temperature of certain parts inside the exoskeleton. **A1:** Trained maintenance person will avoid touching high temperature parts. **R2**	**Acceptable**, as severity is low and the maintenance person can avoid the hazard.	5.7.4
8	Electrical	Touching of electrical connectors with wet hands	Electric shock	**S1:** Contacting an electrically live part causes only minor injury due to low battery voltage. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O2:** Reaching live parts when touching the connector can occur in rare cases. **A2:** Electric shock develops fast and cannot be avoided. **R1**	**Acceptable in principle, but marked for further risk reduction**, as state-of-the-art solutions for this problem exist.	5.2

Table 10 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
9	Ergonomic	Discomfort	Stress	**S1:** The user can feel discomfort from being restrained by the robot. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O1:**. A generally low level of discomfort has been measured in user tests. **A1:** The user can stop using the robot if mental stress is experienced. **R1**	**Acceptable**	5.9
10	Material/ substances	Emission of dust	Pneumoconiosis	**S1:** Emission of a small amount of dust from the braking system can in rare cases lead to minor respiratory problems. **F2:** Dusts can be inhaled whenever the user wears the robot. **O2:** Harmful amounts of dusts can gather if the robot is used over longer time in rooms without ventilation. **A2:** Inhaling cannot be avoided. **R1**	**Acceptable in principle, as the severity is low, but marked for further risk reductions**, as state-of-the-art solutions for this problem are available.	5.7.3

7.4.2.3 Risk reduction measures

During risk assessment, hazards are identified which lead to a risk that is intolerable and needs further reduction. Table 11 shows three selected hazards with measures to reduce the risk thereof.

Table 11 — Risk reduction measures for three selected hazards

#	Hazard and hazardous event	Potential consequence	Inherently safe design measure	Safeguard or complementary protective measure	Information for use
6	Fire hazard of batteries	Burn	State-of-the-art batteries with a design that reduces fire hazard are used (e.g. see IEC 62133-1 and IEC 60335-2-29		Instructions for proper handling and charging of batteries will be included in the user manual.
8	Touching of electrical connectors with wet hands	Electric shock	The connectors are redesigned in a way that touching live parts with a finger is almost impossible		Instructions are added to the user manual to not operate the robot with wet hands.
10	Emission of dust	Pneumoconiosis	Materials and components of the exoskeleton are chosen so that the emission of dust (e.g. from brakes) is as low as possible.		

7.4.2.4 Final risk assessment and residual risk

After all risk reduction measures have been applied, a final risk assessment is performed to determine if risk reduction has been successful and to determine the residual risk. Table 12 shows only the hazards selected in 7.4.2.3.

Table 12 — Final risk assessment

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
6	Electrical	Fire hazard of batteries	Burn	**S2:** Serious burn is possible. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O1:** Due to reliable batteries and proper changing instructions the probability of burn is very low. **A2:** The robot cannot be taken off quickly enough to escape the fire. **R4**	**Acceptable** as the current state of the art does not provide better solutions.	5.3
8	Electrical	Touching of electrical connectors with wet hands	Electric shock	**S1:** Contacting an electrically live part causes only minor injury due to low battery voltage. **F2:** The user is exposed to this hazard whenever the user wears the robot. **O1:** Live parts are concealed in the connector design so that the probability of touching is very low. **A2:** Electric shock develops fast and cannot be avoided. **R1**	**Acceptable** as the severity and probability of harm are sufficiently low.	5.2
10	Material/ substances	Emission of dust	Pneumoconiosis	**S1:** Emission of a small amount of dust from the braking system can in rare cases lead to minor respiratory problems. **F2:** Dusts can be inhaled whenever the user wears the robot. **O2:** Harmful amounts of dust can gather if the robot is used over longer time in rooms without ventilation. **A2:** Inhaling cannot be avoided. **R1**	**Acceptable**, as probability of harm is low.	5.7.3

7.4.3 Safety-related control system

In the risk reduction process, no safeguards using the safety-related control system are implemented. However, the robot is equipped with an emergency stop functionality which allows the robot to be stopped, e.g. when wrong torques are provided by the actuators. Table 13 shows the PL required for the safety function.

Table 13 — Safety function and assigned PL

#	Safety function	Recommended PL according ISO 13482:2014, Table 1	PL according to ISO 13849-1:2015 S: Severity of injury F: Frequency and/or exposure to hazard P: Possibility of avoiding hazard or limiting harm	Clause of ISO 13482:2014
I	Emergency stop	C	**S1:** The user can overpower the robot and only minor injury is expected. **F1:** Situations in which emergency stop is needed are rare. **P2:** As the emergency already happened, evasion is hardly possible. **PLr: b**	6.2.2.2

7.5 Example 4 — Person carrier robot

7.5.1 Overview

This example deals with a self-balancing person carrier robot capable of transporting a single passenger from one place to another.

System architecture:

This robot consists of a steering column, two decks (one for each foot), and two wheels placed under the decks in lateral direction. The robot is without a seat and its passenger can drive the robot standing on the decks.

Specifications:

The robot is 1,2 m to 1,4 m tall (adjustable) and weighs 15 kg. The maximum speed of the robot is 6 km/h. The wheels consist of air-inflated tires.

Operating environment:

This robot is designed to operate indoor on flat floor with slope not exceeding 5°.

Typical tasks:

The task foreseen for the robot is transporting a person from one location to another indoors on a flat surface without any gaps.

The robot is manoeuvred by a user by tilting a steering column in a desired direction of motion.

Degree of autonomy:

The person carrier robot in this working example assumes manual operation. However, the stability control task is permanently autonomously performed by the robot. In combination, it is assumed that the robot operates in semi-autonomous operational mode.

Robot subtype determination:

The robot is categorized as Type 3.1 because it assumes standing single passenger, use on flat surfaces indoor, maximum speed as low as pedestrians, lightweight, and semi-autonomous operation.

7.5.2 Risk assessment

7.5.2.1 Determination of the limits of personal care robot

The following limits are assumed for the robot in this example:

— use on flat surfaces in indoor environments;

— all manoeuvres are conducted by the user on board;

— the person who receives instructions on use and safety functions, as specified by the manufacturer, with no physical disability, uses the person carrier robot;

— the passenger is at least 14 years old;

— the passenger's weight does not exceed 100 kg;

— the maximum travel speed is 6 km/h.

Foreseeable misuse:

The following misuses can be anticipated:

— driving outdoors;

— driving on a slippery floor;

— driving on an uneven terrain;

— driving with heavy load;

— driving in cluttered environment (humans and/or objects);

— touching charging plugs with wet hands;

— reckless driving.

7.5.2.2 Initial hazard identification and risk estimation

Table 14 lists hazards identified for the person carrier robot. The list has been compiled by using ISO 13482:2014, Annex A, as a checklist and discussing for each hazard listed in the annex, if a hazard is present. For the sake of brevity, the list is limited to ten items, although it is possible that there are other hazards to be addressed. In addition, Table 14 shows an estimation of the risk originating from these hazards based on the risk graph in Figure 3.

Table 14 — Risk evaluation before applying risk reduction measures

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation S: Severity of harm F: Frequency of exposure O: Probability of occurrence A: Possibility to evade R: Risk index	Risk evaluation	Clause of ISO 13482: 2014
1	Mechanical	Collision with safety-related obstacles	Chest or leg injury	**S2:** Collision with obstacles at 6 km/h and the effects like losing balance of passenger can lead to serious injuries. **F2:** The user is exposed to this hazard whenever the robot is in operation. **O3:** The hazardous event can happen whenever the robot is in operation. **A1:** Travel speed is equivalent to that of pedestrian, and collision can be avoided. **R: 5**	**Not acceptable**, as both the severity and the probability are high.	5.10.8
2	Mechanical	Tripping or falling due to driving over a bump or gap	Head injury	**S2:** Fall from upright position can lead to serious head injury. **F2:** The user is exposed to this hazard whenever the robot is in operation. **O2:** The hazardous event can happen occasionally when the robot is in operation. **A1:** Hazardous ground conditions can be avoided. **R: 4**	**Not acceptable**, as both the severity and the probability are high.	5.10.3
3	Mechanical	Falling when the robot slips on the floor	Head injury	**S2:** Slipping can lead to serious head injury. **F2:** The user is exposed to this hazard whenever the robot is in operation. **O2:** This hazardous event can happen occasionally when the robot is in operation. **A2:** It is impossible to avoid slipping. **R: 5**	**Not acceptable**, as both the severity and the probability are high.	5.10.3

Table 14 *(continued)*

#	Type of hazard	Hazard and hazardous event	Potential consequence	Risk estimation **S: Severity of harm** **F: Frequency of exposure** **O: Probability of occurrence** **A: Possibility to evade** **R: Risk index**	Risk evaluation	Clause of ISO 13482: 2014
4	Mechanical	Bystanders being crushed between the person carrier robot and floor or walls	Chest injury	**S2:** Collision at 6 km/h can lead to serious injuries. **F2:** Bystanders are exposed to this hazard often when the robot is in operation. **O2:** The hazardous event can happen occasionally when the robot is in operation. **A1:** Travel speed is equivalent to that of pedestrian, and crushing can be avoided. **R: 4**	**Not acceptable**, as both the severity and the probability are high.	5.10.8
5	Mechanical	Collision due to control system malfunction	Head injury	**S2:** Collision can lead to serious head injury. **F2:** The user is exposed to this hazard whenever the robot is in operation. **O2:** The hazardous event can occur only sometimes with mediocre quality robot. **A1:** Travel speed is equivalent to that of pedestrian, and collision can be avoided. **R: 4**	**Not acceptable**, as the severity is high and the probability of occurrence of harm is medium.	5.10.8
6	Mechanical	Falling due to slipping off the decks	Head injury	**S2:** Fall from upright position can lead to serious head injury. **F2:** The user is exposed to this hazard whenever the robot is in operation. **O2:** The hazardous event happens from time to time. **A1:** Travel speed is equivalent to that of pedestrian, and the user can disembark most of the times. **R4**	**Not acceptable**, as both the severity and the probability of occurrence of harm are high.	5.6