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Guidelines for the development and use of safety testing procedures in human-robot collaboration

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European foreword

This CEN Workshop Agreement (CWA 17835:2022) has been developed in accordance with the CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – A rapid prototyping to standardization" and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was approved by a Workshop of representatives of interested parties on 2021-11-24, the constitution of which was supported by CEN following the public call for participation made on 2021-03-26. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

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Introduction

The traditional concept of industrial robots refers to bulky machines, where the robot workspace is physically separated from the operator working area. The concept of collaborative applications reached the industrial domain and was elevated to one of the key-enabling technologies of the Industry 4.0 paradigm. Similar approaches can be nowadays applied to a wide variety of other machines, designed to work closely with humans. At the same time, we are witnessing increasing implementation of service robots in several domains, such as personal care, agriculture and logistics. Moreover, medical equipment and systems based on robotic technologies are more and more implemented in current medical practice and rehabilitation and assistance robots in particular have become relevant, as aging populations are increasingly affected by chronic disabilities.

In general, robot systems and applications characterized by close human-robot interaction (such as collaborative applications in industrial robotics or rehabilitation robots in medical applications) are accompanied by new challenges from the safety perspective (i.e. the potential contact or the intension of contact between human and robot introduces a higher exposure to mechanical hazards). In such cases, ensuring safety is potentially highly complex and variable, depending on the specific implementation scenario and the safety-related measures implemented. The new safety-related challenges need to be properly addressed and validated.

According to robot categorization, standards provide different means to ensure safety in *human-robot collaboration*, and several test methods have been recommended in the last few years, characterized by different levels of detail and addressing different robot categories. Considering the common challenges due to *human-robot collaboration* for various application domains, the objective of this CWA is to provide a framework for compiling testing procedures for the validation of the residual risks related to the mechanical hazards arising in *human-robot collaboration*, by using a category-transversal approach based on standards and on well-established best practices. The following stakeholders can benefit from this CWA:

— for industrial robots: integrators or users planning the evaluation of specific mechanical hazards of a certain collaborative application, considered as a whole;

— for the medical robotics field: manufacturers planning the residual risk evaluation (where not diversely indicated by EN ISO 14971:2020 and CEN ISO/TR 24971:2020), as part of the risk management process, or other users planning the evaluation of the mechanical hazards in some use scenarios;

— for service robots: manufacturers or other professional users planning the evaluation of the mechanical hazards in some use scenarios.

The systematic pooling of practices and information belonging to different robot categories can significantly expand the base of knowledge available for the stakeholders. As an example, ISO/TR 23482-1:2020 refers to ISO/TS 15066:2016 for the data of pain onset for physical contacts and EN IEC 80601-2-78:2020 refers to EN ISO 13482:2014 for the consideration of risk reduction measures for robot collision with safety-related obstacles. This document intends to provide methodology and criteria to support stakeholders in the consistent development and use of uniform, transversal testing procedures for mechanical safety. Applicability of these transversal testing procedures may facilitate demonstration of compliance for applications where multiple legislation, or parts of legislation, may apply, e.g. when a medical robot should comply also with machinery-specific requirements.

The evaluation of risks in human-robot collaboration may be variable and requires specific assessment. The *system-level validation* addressed in this document targets the risks characterizing a robot implementation or robotic application; although it may be considered that mechanical safety is not the only relevant dimension of safety when dealing with *human-robot collaboration* [1], the document is limited to the scope of mechanical hazards.

1 Scope

This document gives guidelines for a uniform framework, transversal with respect to the different robot categories and limited to those robots and robotic applications characterized by *human-robot collaboration*, for the development and/or use of testing procedures, applicable to different robot categories and use scenarios.

This document is informative and is not aimed at substituting or simplifying verification and/or validation procedures required by standards. The objectives of this document are the following:

— define an approach for the development and use of procedures for testing safety in *human-robot collaboration* at a system level, based on *safety-relevant human-robot collaboration skills* and limited to the mechanical hazards;

— define a comprehensive list of application-driven, technology-invariant *safety-relevant human-robot collaboration skills* valid across different domains;

— provide a template for *system-level validation protocols*;

— by way of example, present two *system-level validation protocols*, applicable to multiple domains.

This document does not apply to the following devices, systems and applications: autonomous vehicles for the transportation of persons, drones, rescue robots (including ground, marine and aerial vehicles), surgical robots in relation to the body of the patient, passive wearable devices, external limb prostheses.

NOTE 1 This document aims at providing harmonization in the compilation of structured testing procedures, to supplement safety validation of specific robot applications, building, where possible, on test methods provided in the relevant standards. It does not propose any safety requirement, nor is it intended to provide alternatives for or simplification of the relevant standards for each robot category. Users of this document are expected to be proficient in directives, regulations and standards applicable for the specific robot system and application. An overview of robot categorization is provided in A.1.

NOTE 2 This document does not address “functional safety” (e.g. the performance level of safety-related parts of control systems), nor criteria for its validation and verification.

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 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 https://www.electropedia.org/

EN 16271, *Value management - Functional expression of the need and functional performance specification - Requirements for expressing and validating the need to be satisfied within the process of purchasing or obtaining a product*

EN 62304, *Medical device software – Software lifecycle processes*

EN 62366-1, *Medical devices – Part 1: Application of usability engineering to medical devices*

EN ISO 3691-4:2020, *Industrial trucks — Safety requirements and verification — Part 4: Driverless industrial trucks and their systems*

EN ISO 10218-1, Robots and robotic devices — Safety requirements for industrial robots — Part 1: Robots[1]

EN ISO 10218-2, Robots and robotic devices — Safety requirements for industrial robots — Part 2: Robot systems and integration[2]

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

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

EN ISO 13855, *Safety of machinery — Positioning of safeguards with respect to the approach speeds of parts of the human body*

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

EN ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

EN ISO 14971:2020, *Medical devices – Application of risk management to medical devices*

EN ISO 18497:2018, *Agricultural machinery and tractors – Safety of highly automated agricultural machines - Principles for design*

CEN ISO/TR 24971:2020, *Medical devices — Guidance on the application of ISO 14971*

EN IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

EN IEC 80601-2-78:2020, *Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation*

EN IEC 80601-2-77:2021, *Medical electrical equipment — Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment*

ISO 8373:2021, *Robots and robotic devices – Vocabulary*

ISO/DIS 10218-1.2:2021, *Robotics – Safety requirements – Part 1: Industrial robots*

ISO/FDIS 10218-2:2021, *Robotics – Safety requirements – Part 2: Industrial robot systems, robot applications and robot cells*

ISO 18646-1:2016, *Robotics — Performance criteria and related test methods for service robots — Part 1: Locomotion for wheeled robots*

ISO 18646-2:2019, *Robotics — Performance criteria and related test methods for service robots — Part 2: Navigation*

[1] Under preparation. Stage at the time of publication: ISO/DIS 10218-1.2:2021.
[2] Under preparation. Stage at the time of publication: ISO/FDIS 10218-2:2021.

ISO 18646-3:2021, *Robotics — Performance criteria and related test methods for service robots — Part 3: Manipulation*

ISO 18646-4:2021, *Robotics — Performance criteria and related test methods for service robots — Part 4: Lower-back support robots*

ISO 19649:2017, *Mobile robots – Vocabulary*

ISO/TS 15066:2016, *Robots and robotic devices – Collaborative robots*

ISO/TR 23482-1:2020, *Robotics — Application of ISO 13482 — Part 1: Safety-related test methods*

ISO/TR 23482-2:2019, *Robotics — Application of ISO 13482 — Part 2: Application guidelines*

IEC/TR 60601-4-1:2017, *Medical electrical equipment — Part 4-1: Guidance and interpretation — Medical electrical equipment and medical electrical systems employing a degree of autonomy*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8373:2021, EN ISO 12100:2010 and the following apply.

3.1
human-robot collaboration (HRC)
human-robot interaction in a shared space in which contact with robots, workpieces, loads, or instruments is either prevented or envisaged but harmless

3.2
safety-relevant human-robot collaboration skill (HRC skill)
abstract representation (model) of the ability of an HRC application to reduce a risk defined irrespective of the way it is implemented, be it due to an inherent design feature or a dedicated risk reduction/risk control measure/strategy/policy

Note 1 to entry: an HRC skill can be achieved by the implementation of risk reduction measures or risk control measures, depending on the application domain and the applicable requirements.

3.3
system-level validation of a safety-relevant human-robot collaboration skill
system-level validation (SLV)
test-based assessment of the behaviour of a complete system with regards to pass/fail criteria for a given HRC skill, considering the real use conditions

Note 1 to entry: pass/fail criteria are defined prior to SLV, considering the robot category and the specific risk assessment.

Note 2 to entry: The SLV may be performed on a subsystem for practical reasons, if this is representative of the behaviour of the complete system from the perspective of the HRC skill under consideration.

3.4
system-level validation protocol
SLV protocol

step-by-step instruction for executing validation measurements; it specifies testing procedures for SLV

3.5
residual risk
risk remaining after risk control measures or after all the protective measures have been implemented

Note 1 to entry: For the mere purposes of this document, this definition combines the "residual risk" definitions provided in EN ISO 12100:2010, 3.13, and in EN ISO 14971:2020, 3.17, in order to address industrial robots, service robots and medical robots.

Note 2 to entry: For any other purpose, the above mentioned definitions apply.

3.6
risk control
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

[SOURCE: EN ISO 14971:2020, 3.21]

3.7
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

[SOURCE: EN ISO 14971:2020, 3.24]

3.8
utilizer
either the operator of a robot application or, if applicable, the beneficiary of the service/medical treatment provided by a personal care robot or a medical robot

3.9
user
entity that uses HRC applications and is responsible for the safety of the utilizer(s)

3.10
integrator
entity that designs, provides, or assembles robot systems, robot applications, or industrial robot cells and oversees the safety strategy, including the protective measures, control interfaces and interconnections of the control system(s)

Note to entry: The integrator can be a manufacturer, assembler, engineering company or the user.

[Adapted from ISO/FDIS 10218-2:2021, 3.1.7.2]

3.11
collaborative application
application of industrial robots or industrial robot systems that contains one or more collaborative task(s)

Note 1 to entry: Collaborative applications can include non-collaborative tasks.

[Adapted from ISO/FDIS 10218-2:2021, 3.1.1.6]

4 Transversal “system-level” validation

Human-robot collaboration (HRC) occurs when the spaces designated for the simultaneous operation of human beings and robots are either not defined or there are intentional overlaps among them and there is any possibility of harmless contact (whether intended or not) between human and robot (or, depending on the application, with workpieces, tools, instruments). The possibility of human-robot contact is translated to the onset of further mechanical hazards related to human-robot mutual movements and the forces the robot may exert. Depending on the specific hazardous scenario, these hazards can consist in simple impacts, crushing, trapping, pinching, shearing, entanglement, involving different parts of the human body and of the robot.

Annex A (informative) provides a non-comprehensive overview of robot categorization based on definitions in standards and reference to some of the relevant standards for safety-related processes. HRC, as defined in this document, is typical for the majority of service robotics applications. Depending on the application, any utilizer of a medical robot may be involved in HRC. Concerning industrial robots, HRC is typical of collaborative applications. It follows that HRC-related hazards may occur with different types of robotic devices and in diverse scenarios and environment, including working or daily living activities, indoor or outdoor applications, involving expert or non-expert – trained or untrained – utilizers.

Depending on the specific category and application, there are different available guidelines on how to conduct risk assessment, design, verification and/or validation, primarily provided in harmonized standards. Focusing on safety in HRC from the perspective of the mechanical hazards, some verification and/or validation processes indicate test methods, which, considering the different robot categories separately, are provided in different types of documents and with different levels of detail.

Regardless of the category they belong to, all HRC applications feature mechanical risks inherently related to the specific task or activity. This introduces a common perspective between industrial and service robots, as one fundamental difference, which is the different level of human-robot interaction, lapses. At the same time, some mechanical hazards related to the operation of medical robots can be analogue to those characterizing personal care service robots or industrial collaborative robots, especially when considering both patient and therapist/doctor perspectives during operation of a medical robot. Such a perspective is supported by the cross-reference examples between standards belonging to different robot categories (e.g. ISO/TR 23482-1:2020 referring to ISO/TS 15066:2016 and EN IEC 80601-2-78:2020 referring to EN ISO 13482:2014).

The mentioned risks are diverse and highly variable, as the HRC, sometimes even occurring in an unstructured operational space, can be extremely variegated. This can generate uncertainty about the safety-related assessment of the risk when the change in use conditions may lead to different risk levels. The concept of “system-level validation of a safety-relevant human-robot collaboration skill” (system-level validation, SLV) aims at the assessment of the residual risk for a specific implementation, from the perspective of HRC-related mechanical hazards. The SLV targets the application as a whole, considering its implementation and the modalities of human-robot interaction, in the actual hazardous scenarios (i.e. configuration, state of the involved bodies, conditions, etc.) identified in the risk assessment phase.

NOTE For industrial robots and service robots, the residual risk here considered is the one after all the protective measures have been implemented and SLV is intended to be suitable for users or – where relevant – integrators, considering the risk reduction process provided by the EN ISO 12100:2010. In the case of medical robots, the SLV is intended to be either part of the evaluation of the residual risk, as per the risk management process prescribed by the EN ISO 14971:2020 and detailed in the CEN ISO/TR 24971:2020, or conducted on a released product in use.

The procedures for SLV are referred to as “system-level validation protocols”, described in Clause 6 and can be developed as systematic documents addressing all the SLV-related aspects. To cope with the continuous increase of types of HRC applications, SLV protocols should be developed to be transversal with respect to robot application domains. To this aim, the concept of “safety-relevant human-robot

collaboration skill" (HRC skill) is introduced in this document (see Clause 5); SLV protocol relevance with respect to a HRC application can be based on the combination of the type of robot device and the relevant HRC skill, rather than the robot category.

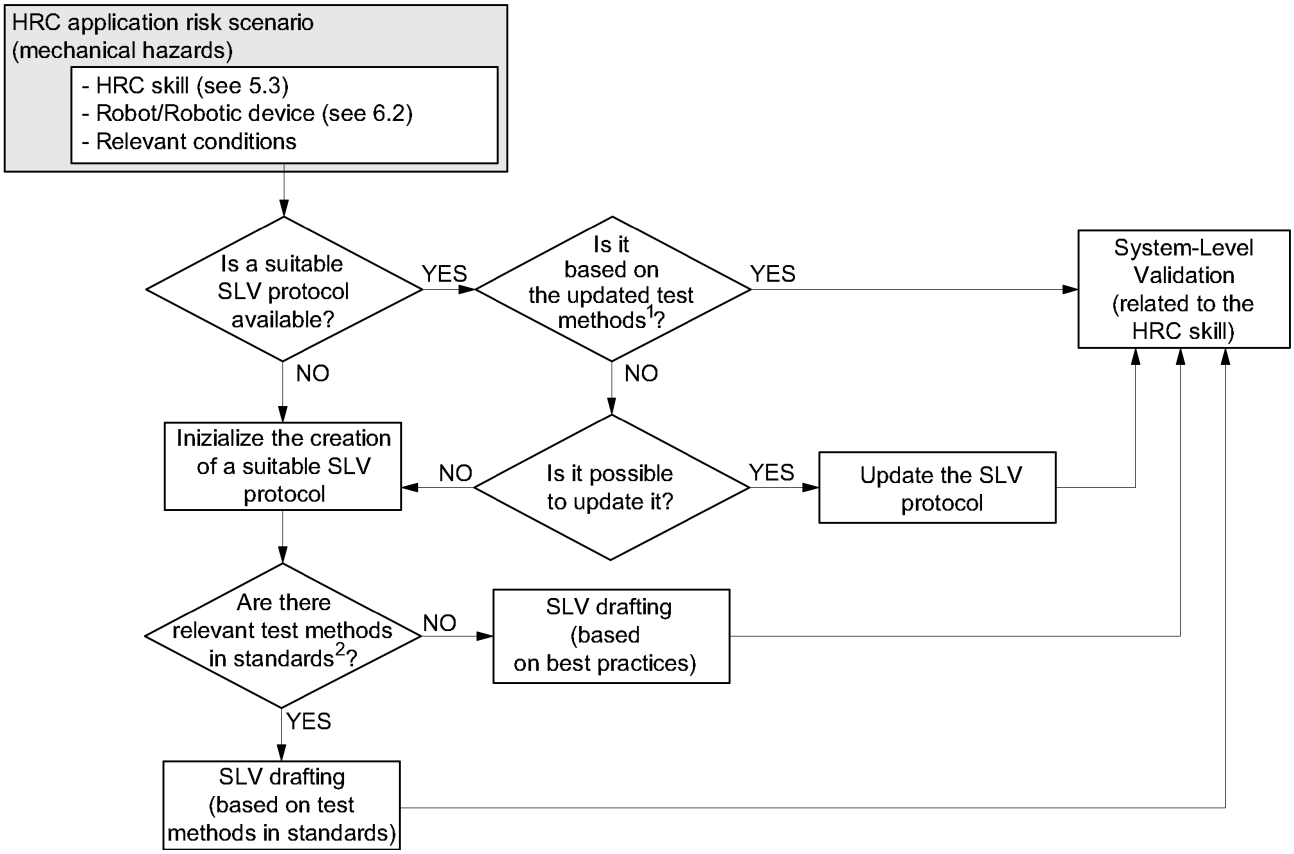
SLV protocol can be technically based, in order of priority, on (see Figure 1):

— Verification and/or validation test methods described in standards or technical reports related to the specific robot category and subcategory under examination;

— Verification and/or validation test methods described in standards or technical reports non-specific for the robot category under examination, but relevant for the application from the perspective of the type of HRC and related hazards;

— Well-established best practices and technologies relevant for the specific application.

A list of test methods available in standardization documents is reported in Annex B (informative).



Key

1 Giving priority, in order, to: standards relevant for the specific robot category, other standards, best practices

2 Giving priority to standards relevant for the specific robot category

Figure 1 — SLV protocol development

5 Cross-category HRC skills

5.1 General

In order to simplify system level validation and enable a cross-category approach, the concept of HRC skills is introduced. HRC skills are defined as abstract representations of an ability of an HRC application to reduce a risk (see 3.2).

The concept of HRC skills is fundamental to define a unified framework for SLV protocols and mutualise their development. An HRC skill is abstract as it does not depend on the way it is achieved but only on the safe target behaviour it describes. HRC skills are transversal to different types of devices and are technically neutral. Once all the risk reduction measures are implemented in a specific application, the relevant HRC skills should be further defined as functional specifications of the expected behaviour of the system.

NOTE Functional specification is generally well adopted in engineering and has been developed in value analysis (EN 16271) and design engineering methods.

5.2 An example: Limit Range of Movement

Considering a generic robotic manipulator for which a certain zone is forbidden for safety reasons, the appropriate HRC skill for SLV is “limit range of movement”, with the limit defined as a 3D space.

The hazards covered by this HRC skill may be of various nature, such as:

a) collision of the robot or of the robot tool with the operator or other humans passing in this zone;

b) operator working with the robot in non-ergonomic posture, involving possibly hazardous movements;

c) over-stretching the limbs of the utilizer of a rehabilitation robot.

These three cases are illustrated in Figure 2.

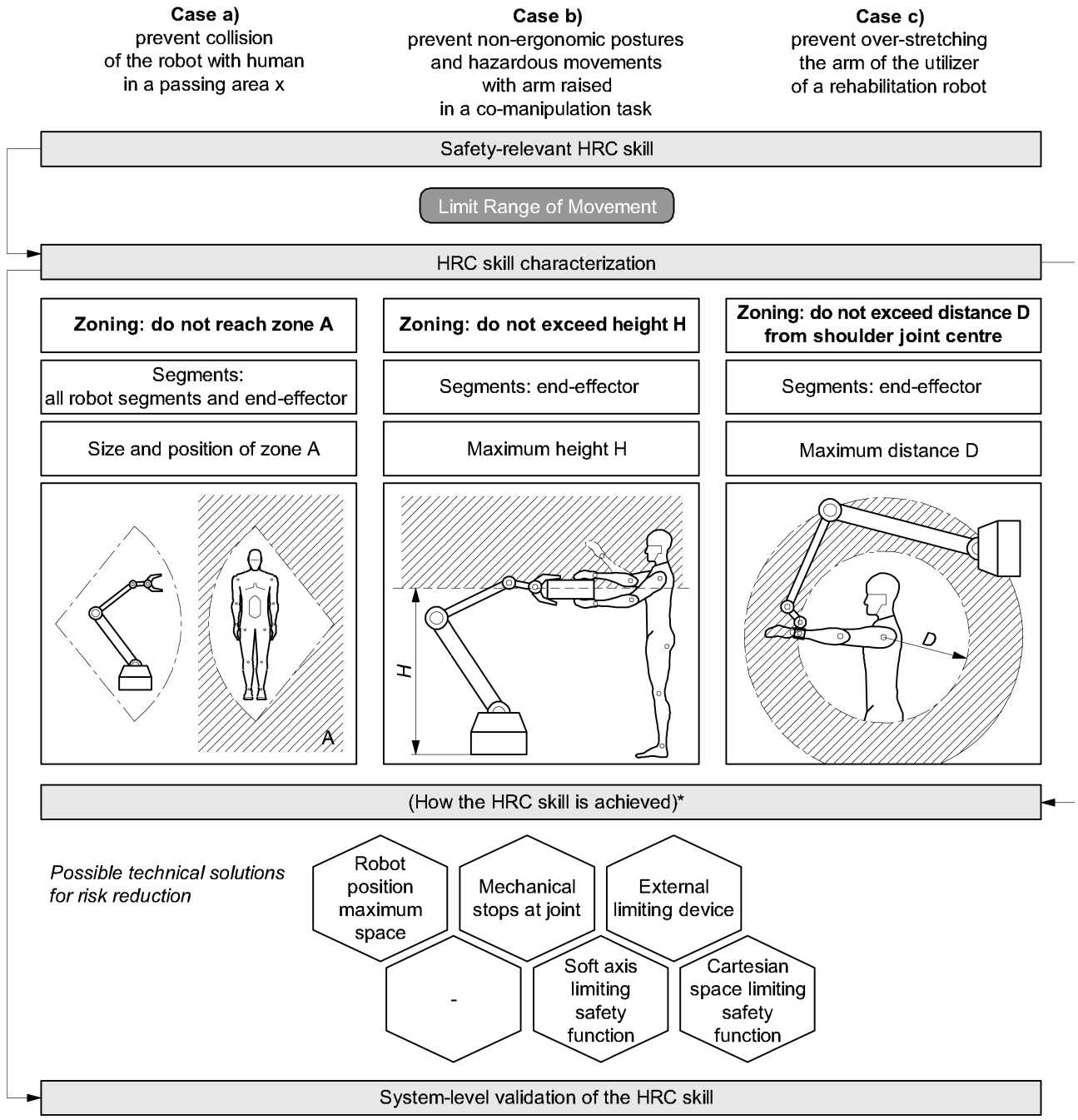
The achievement of the HRC skill can rely on different means and technical solutions, from inherently safe design measures to safeguarding measures, such as control system safety functions. The range of possible solutions is wide, although, at a stage of technological development, some may be predominant for a given type of robot. The HRC skill “limit range of movement” can be achieved, for instance, by positioning the robot manipulator so that the maximum space of the robot does not overlap the hazard zone. This can be considered as an inherently safe design measure. Similarly, when using a rehabilitation robotic arm, the patient position with respect to the robot may be a way to forbid overstretching. Limiting the robot joint(s) range of movement can be realized by mechanical stops or by software (“limiting robot motion” in ISO/DIS 10218-1.2:2021). Cartesian space limiting is indeed commonly provided by robot manufacturers, but other solutions, using an external device, are also possible. Finally, a given HRC skill can be achieved by combining different technical solutions.

Therefore, an HRC skill assumes a specific characterization depending on the use scenario. The HRC skill “limit range of movement” can be characterized by the nature of the space limit, its shape and position and, in case of a 3D space limit, the part(s) of the robot system affected (e.g. only the end-effector or all robot parts). Once characterized for a specific HRC application, the HRC skill expresses the safety-related target behaviour, still remaining neutral with respect to the technical solution(s) implemented to reduce the risks.

Before using the system in a given application, it should be checked if the technical solution is in place and the safety-related target behaviour, as it is characterized for the specific use case, is achieved. This can be done by a physical test, i.e. performing a SLV.

Even when risk reduction relies on inherently safe design measures (e.g. based on the positioning of the robot in a case relevant for the HRC skill “limit range of movement”), it could be possible that the HRC skill is not properly achieved, due to differences in the effective placement of the robot at the installation, or due to changes in the environment, making the forbidden region inappropriate. Testing the system in the real use condition, even with a simple test, can be relevant even if safety relies on a safety function. In this case, the aim of SLV is not to test the performance level of the safety function (provided by the manufacturer), but to check that the safety function, as configured, is appropriate to achieve the system target behaviour from the perspective of the relevant HRC skill (i.e. to achieve the HRC skill).

Particularly useful in the HRC skill concept is that the same test method may be used for a given HRC skill, regardless the technical solution(s) used for risk reduction.



Key

* The identification of appropriate risk reduction measures or risk control measures is out of the scope of this document and covered by the relevant standards.

Figure 2 — Example of the HRC skill "limit range of movement", with three application cases corresponding to different hazards.

5.3 Description of HRC skills

5.3.1 List of HRC skills

The HRC skills identified so far [2] include:

- Limit Physical Interaction Energy;
- Maintain Safe Distance;
- Dynamic Stability;
- Limit Range of Movement;
- Maintain Proper Alignment;
- Limit Restraining Energy.

By properly considering the HRC skills from this list, it is possible to address the HRC-related risks arising in the different collaborative operation modes (as per ISO/TS 15066:2016), as well as those possibly generated and relevant in several HRC application (e.g. some mechanical risks listed in EN IEC 80601-2-78:2020 are covered).

Each HRC skill can be valid for several robot categories, robotic devices and their applications. HRC skills are suitable for the SLV. They are described in the following sub-sections.

As further explained in 6.2, not all robots are expected to benefit from the application of each HRC skills, as their applicability depends on the specific application scenario and safety requirements (e.g. the relevance of HRC skills in the rehabilitation robotics domain is described in [3]).

5.3.2 Limit Physical Interaction Energy

The HRC skill “limit physical interaction energy” aims to ensure the absence of injuries in case of physical contact between the robot and humans involved in the interaction. It applies to all the unintended contact situations, either transient or quasi-static, which are identified in the risk assessment - due to intended use or foreseeable misuse.

Pain onset thresholds for human-robot collision have been proposed for forces and pressure in ISO/TS 15066:2016, based on biomechanical studies and are reported in ISO/FDIS 10218-2:2021. Energy thresholds are not defined independently, but are obtained from the force thresholds. Energy can be a more physically appropriate measure to describe the risk for some injuries, such as fractures.

NOTE: when intentional physical contact is part of the operating mode (e.g. in hand guiding mode), the limitation of forces is not aimed for safety but rather for usability, and as such is not considered from the perspective of the HRC skill “limit physical interaction energy”.

5.3.3 Maintain Safe Distance

The HRC skill “maintain safe distance” defines the ability of the robotic system to maintain a safe distance with respect to humans. It can be based on monitoring the distance, and avoiding contact by stopping or modifying its path, possibly adapting the speed to the distance. This HRC skill includes also the basic ability to stop following a safety signal or the activation of an emergency stop button.

NOTE In all robots, a stop function is implemented.

5.3.4 Dynamic Stability

The HRC skill “dynamic stability” defines the ability of the robot system to avoid falling over, possibly harming a person. It generally concerns mobile robots, possibly equipped with a robotic arm or an

effector. The word “dynamic” here means that the robot should be stable under dynamic conditions, during movement of the robot itself and/or that of the integrated robotic devices.

NOTE This HRC skill includes the static case as a subcase.

5.3.5 Limit Range of Movement

The HRC skill “limit range of movement” can be applicable either to limit the space reached by the robot, or to limit some of its trajectory features such as speed, acceleration, curvature and jerks.

When dealing with space limiting, the limit can be defined in various ways. For instance, the limit can be based on axis position or can be defined based on end-effector position. It can be also applied to different parts of the robot (all or some segments, end-effector or work piece). Space limits and other limits relevant for limiting the range of movement can be linked, for instance when a speed limit is defined for certain spaces of the robot workspace.

5.3.6 Maintain Proper Alignment

The HRC skill “maintain proper alignment” aims to ensure a kinematic compatibility between the movement provided by the system and the human joint axes.

This HRC skill is relevant when a robotic device or joint with limited degrees of freedom acts in parallel with a human joint. This configuration is found in particular in exoskeletons, those used as physical assistants in different application domains and those used as rehabilitation robots. However, it can also be applied in rehabilitation robotics with a robot that is not an exoskeleton, when a human joint is mobilized by the robot. This is challenging, as the human joints have complex kinematics depending on bone geometry, but also varying based on many biomechanical and neurological factors.

NOTE From the design perspective, this is addressed by manufacturers of rehabilitation robots and exoskeleton with various strategies, such as joint design characterized by human-like kinematics and accurate placement and design of the brackets between human limbs and the rehabilitation system, including some compliance to compensate for any kinematic mismatch.

When misalignment occurs, it produces forces in the attachment; limiting these forces is considered within the concept of HRC skill “limiting restraining energy”. The HRC skill “maintain proper alignment” considers the misalignment itself and possible effects on the musculoskeletal system.

NOTE In rehabilitation robotics, HRC skill “maintain proper alignment” addresses the mechanical hazards associated with misalignments as indicated by EN IEC 80601-2-78:2020.

5.3.7 Limit Restraining Energy

When one or more limbs of the utilizer are strapped to a robot and either are moved by the robot or the movement is the result of a shared human-robot control, forces and pressures are transmitted to the restrained part of the human body, possibly causing harm. This can either be at the interface, where continuous/repetitive pressure and shear can cause discomfort or injuries, or at the musculoskeletal level, where excessive forces and torques can also cause injuries. The HRC skill “limit restraining energy” corresponds to limiting the level of those loads. The relevance of such a HRC skill is also related to the spread of wearable robots in different application domains (e.g. industrial), beyond the medical one.

6 System-Level Validation Protocols

6.1 General

A SLV protocol is a step-by-step instruction for executing testing measurements; it specifies the procedures for SLV and is developed in the form of a document.

SLV requires to assess the safety features of the HRC application from the perspective of a specific HRC skill, providing evidence of the effectiveness of the combined safety measures implemented, possibly with reference to the relevant standards. Such an assessment is not a trivial task, as it requires, in order:

1) a comprehensive knowledge of the applicable regulation landscape;

2) critical awareness of the relevant physical metrics and performance data to be measured;

3) technical knowledge of the most appropriate testing equipment and methodologies;

4) the production of clear, complete, and self-explanatory reports.

Depending on the robot category, risk assessment or risk management are fundamental preliminary steps for identifying the residual risk, which is the input information of the SLV. The relevant hazardous situation and testing conditions depend on the specific installation, environment, task, utilizer awareness, protective or risk control measures, etc.

A SLV protocol should reflect the current state of the art in the validation of a specific HRC skill for a HRC application. It describes the SLV in the context of a type of application. It gives contextual information on assumptions and factors which are critical for SLV. Furthermore, it formalizes both target metrics and how to measure them. It describes procedures for how to perform experiments and provides forms to report the measurement results.

6.2 SLV protocol identification

To exploit the potential of the category-transversal approach, SLV protocols should be general procedures, applicable in several domains and individuated only by two fundamental variables, that are the HRC skill to be achieved and the type of robot or robotic device involved in the specific HRC application. A first nucleus of robots and robotic devices which can be implemented in HRC applications is the following:

— Robotic arm (e.g. an industrial manipulator, a robotic arm used for rehabilitation, etc.);

— Mechanical Gripper (an end-effector type, considered separately as it may be characterized by specific hazards);

— Mobile robot (e.g. an autonomous mobile robot, a mobile agricultural robot, a mobile servant robot, etc.);

— Mobile robotic arm (i.e. a mobile platform with a manipulator);

— Exoskeleton (e.g. RACA robot type or wearable robot for augmentation, support etc.);

— Actuated balance trainer (e.g. mobile or stationary platform for balance exercises);

— Weight support (e.g. body weight support for rehabilitation).

In Table 1, a correlation matrix is reported, identifying the possible relevance of each HRC skill in relation to the different robotic devices. The correlation dots indicate the possible necessity of a SLV protocol,

identified by the correspondent HRC skill and robotic device. The actual relevance of each combination depends then on the specific use application scenario (i.e. the nature of HRC-related risks identified).

More SLV protocols may be developed based on the same combination of HRC skill and robot or robotic device, considering the use of different measuring equipment. Likewise, there can be specific operation conditions, which can vary depending on task design or the context of use, leading to different testing approaches. These aspects result in the development of SLV protocol variants for the same combination of HRC skill and robot or robotic device.

Table 1 — Possible combinations of HRC skills and robots/robotic devices

Robots/Robotic devices	HRC skills					
	Limit physical interaction energy	Maintain safe distance	Dynamic stability	Limit range of movement	Maintain proper alignment	Limit restraining energy
Robotic arm	•	•		•		•
Mechanical gripper	•			•		
Mobile robot	•	•	•	•		
Mobile robotic arm	•	•	•	•		
Exoskeleton	•			•	•	•
Actuated balance trainer	•		•	•	•	•
Weight support	•		•	•	•	•

6.3 Contents of a SLV protocol

Table 2 reports a possible structure of contents for the development of SLV protocols. A detailed suitable template is reported in Annex C.

Table 2 — General contents of a SLV protocol

Section	Contents
Introduction	— Scope and limitations — Definition and terms
Concept and objectives	— Characterization of hazards to consider for HRC skill validation — Target metrics: physical, measurable quantities that the SLV depends on, in relation to a specific risk reduction level
Conditions	— System, environment, other relevant aspects
Test setup	— Description of test equipment and test method
Procedure	— Test plan — Test preparation — Step-by-step testing procedure — Practices for data analysis — Instruction on how to document the SLV
Bibliography	— Relevant standards and other references
Annexes	— Reporting templates and eventual further relevant information

An "introduction" section may define the HRC skill, the system under test (e.g. a robotic arm), a sub-system (if any, e.g. an end-effector), conditions – in terms of environment – and importantly the measurement devices required for validation.

The "concepts and objectives" section may report information on relevant hazards and parameters (e.g. joint angles of a robot, velocities etc.). Furthermore, one or more metrics should be defined, based either on observation (Boolean variables) or on physical and measurable quantities. These quantities should be the output variables for the validation. The SLV protocol should identify target metrics, whose values are the benchmarks indicating if the residual risk is actually acceptable for the HRC application under examination. They sometimes represent a criterion, such as a threshold, that test output values should not exceed for considering the test as passed (predicates).

The "conditions" section may report the conditions influencing the hazardous situation and the factors that have a significant impact on the test results (output values). If there are sub-systems (e.g. a robotic arm on a mobile platform), then a description of conditions (sub-system parameters) that have a significant impact on the target metrics should be included. The environment should be described through the environmental conditions which have a significant influence on the validation results (e.g. inclination or surface conditions).

The "test setup" section may describe how the test is to be performed. That is accomplished through a description of the test arrangement (e.g. how to arrange the sensors and the system within the test environment) and the sensing devices (e.g. load cells, photo sensors, etc.), including also necessary calibrations.

The “procedure” section may provide the step-by-step procedure for the test execution and the data acquisition, including instructions for recording, logging, and pre-processing (filtering, offset compensation) sensor data. Furthermore, it defines which data analysis to perform, including instructions for interpreting the results. Finally, reporting is exemplified.

The “bibliography” may be relevant for traceability of the SLV protocol normative and non-normative references.

The “annexes” section may contain reporting templates and other relevant information.

6.4 SLV protocol examples

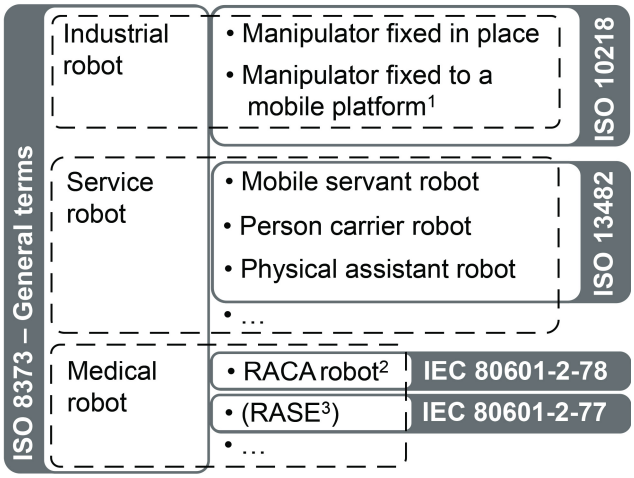
In Annex D, an example of SLV protocol is reported, for the SLV of a mobile robot HRC application from the perspective of the HRC skill “maintain safe distance” by measurement. It can be applied to mobile robot systems used in different indoor environments. The application of “maintain safe distance” in this case is in the form of preventing collisions between the robot and human bodies. The SLV protocol validates that a certain stopping distance is never exceeded by a mobile robot system detecting objects and triggering a stop consequently.

The scope of another SLV protocol example reported in Annex E is the SLV, from the perspective of the HRC skill “limit range of movement”, of an HRC application based on a manipulator used either for a hand guiding application or for rehabilitation purposes, with a limb of a subject having a connection point with the robot (either free or restrained) and that point moving within a 3D volume under a shared human-robot control.

Annex A(informative)
Overview of robot categories and safety-related processes

A.1 Robot categorization

Robots and robotic devices are used with different purposes and in different application fields. Based on several relevant definitions, provided in EN ISO 8373:2021, in relevant standards from the IEC 60601 series and in ISO 13482:2014, the non-comprehensive categorization reported in Figure A.1 is obtained.



Key

1 a mobile platform with or without manipulators is defined as a mobile robot
2 medical robots for rehabilitation, assessment, compensation or alleviation (EN IEC 80601-2-78:2020)
3 robotically assisted surgical equipment (EN IEC 80601-2-77:2021)

Figure A.1 — Non- comprehensive categorization of robots based on relevant definitions. RASE represent an exception among medical robots, as explained in A.3.

With a few exceptions, robots are within the scope of the Directive 2006/42/EC on machinery (Machinery Directive, MD) [4], defined as composed of linked parts or components, with at least one of which moving, and being actuated by a drive system. A programmable robot supplied by a robot manufacturer is regarded by the Machinery Directive as a "partly completed machinery" if it is not intended to perform a specific application (e.g. industrial robots). To be considered as a "completed" machinery, it should be designed for or integrated in a specific application.

Due to the different design and safety-related approaches, medical robots fall primarily within the scope of Regulation 2017/745: Medical Device Regulation (MDR) [5]. According to the MDR, they have to comply also with health and safety requirements of the MD, in cases in which hazards covered by MD are relevant and the MD requirements are more specific than the general safety and performance requirements provided in the MDR.

Other directives may also apply, such as: 2014/35/EU (Low Voltage Directive, LVD) [6], 2014/30/EU (Electromagnetic Compatibility Directive, EMCD) [7], 2014/53/EU (Radio Equipment Directive, RED) [8]. 2001/95/EC (General Product Safety Directive, GPSD) [9] and 85/374/EEC (Directive on Liability of Defective Products, LDP) [10] also apply to robots dedicated to consumer markets. When meant to be implemented in some hazardous environments, other directives may apply, such as ATEX Directive 2014/34/EU [11] and Regulation 1907/2006 (REACH) [12]. Robot applications involving workers should comply with 89/391/EEG (OSH Framework Directive) [13].

The following sub-clauses of this Annex provide an overview of the most relevant standards from the perspective of mechanical safety for different robot categories.

A.2 Industrial and service robots

A.2.1 General

Fulfilling the essential health and safety requirements, as indicated by the MD, for the design and construction of machinery is based on an iterative process of risk assessment and risk reduction for which one should rely on EN ISO 12100:2010 (type A standard). Such an iterative process starts with the risk assessment, which is strictly related to the defined limits and the intended use of the machine, including reasonable foreseeable misuse, and relies on the protective measures implemented by the manufacturer, the integrator (if present) and the user. The former should be responsible for i) inherently safe design measures, ii) safeguarding and complementary protective measures and iii) information for use, to be applied with this hierarchical order. The user, in turn, should implement protective measures based on information provided by the manufacturer and adopts other measures, as responsible of organization, provision and use of additional safeguards, use of personal protective equipment, training, etc. The implementation of all the risk reduction measures does not prevent the existence of residual risks; these should be assessed to verify the acceptability for the specific application.

A.2.2 Industrial robots

The most relevant type C documents to be considered for industrial robots are EN ISO 10218-1 and EN ISO 10218-2, focused on robots (1) and robot systems and integration (2), respectively.

ISO/DIS 10218-1.2:2021 reports a list of significant hazards derived from EN ISO 12100:2010 and corresponding requirements for robots before the integration in a robot system, which are explained in the document. The acceptable methods for the verification and validation of safety requirements and protective measures are also reported.

In ISO/FDIS 10218-2:2021, a list of significant hazards for robot systems and applications is reported. In the verification and validation of safety requirements and protective measures, a list of verification and validation methods is provided; the acceptable methods are also indicated in relation to the specific safety measures.

Collaborative applications are outlined in ISO/DIS 10218-1.2:2021 and ISO/FDIS 10218-2:2021; the latter incorporates also contents of the ISO/TS 15066:2016, such as the determination of the acceptable biomechanical limits for human-robot contact scenarios. Guidelines for the validation of power and force limiting collaborative applications by the measurements of force and pressure are also reported.

The EN ISO 3691-4:2020 (type C) should be considered for safety requirements and verification of driverless industrial trucks and their systems, including also autonomous mobile robots. Safety requirements and/or protective risk reduction measures are provided in the standard, as well as the description of testing procedures, which can be relevant considering the HRC perspective.

A.2.3 Service robots

Service robots perform tasks that are useful for humans and differ from traditional (i.e. non-collaborative) industrial robot applications due to the following aspects:

— The level of human-robot interaction, which can be higher in physical and cognitive terms;

— The type of task, which is much more heterogeneous;

— The environment, which can be unstructured;

— The possibility of interacting with non-expert utilizers.

Due to the variety of applications in which service robots are implemented according to the existing subcategories, safety requirements can vary substantially. Accordingly, at the time of publication of this document, there are no Type C standard dealing with safety requirements applicable to all service robots.

In standards from the ISO 18646 series, several test methods are reported for the performance assessment of service robots. In those standards, it is explicitly claimed that the provided performance criteria are not to be interpreted for the verification or validation of safety requirements. However, some of the performance criteria may influence the safety, and some of the test methods may be considered when testing safety.

A.2.4 Personal care robots

Personal care robots are specific service robots aimed at enhancing the quality of life of utilizers and are characterized by the following features (as per ISO/TR 23482-2:2019):

— they are mostly mobile and there are no guards limiting their work among humans;

— human-robot interaction, even physical, is essential;

— they are often characterized by a degree of autonomy to work and take decisions autonomously.

The reference type C standard which should be considered is the EN ISO 13482:2014, addressing risk assessment, safety requirements and protective measures, safety-related control system requirements, verification and validation methods, among which there are also “practical tests” and “observation during operation”. The standard specifies that after the adoption of the inherently safe design and protective measures, the acceptability of the residual risk should be proved.

ISO/TR 23482-1:2020 describes several test methods to verify the compliance to requirements of EN ISO 13482:2014. ISO/TR 23482-2:2019 provide “Application guidelines” for ISO 13482:2014. The proper risk reduction methodology is contextualized within the ISO 12100:2010 approach and several working examples are provided.

A.3 Medical robots

The MDR emphasizes safety and performance during the entire lifetime of medical devices, including post-market evaluation. As per EN ISO 14971:2020, the risk management should address all the safety-related processes. Risk management is under the responsibility of the sole manufacturer, as medical devices are produced with specific intended use(s). The risk management plan should cover: i) risk analysis, ii) risk evaluation, iii) risk control, iv) evaluation of the overall residual risk, v) risk management review and vi) production and post-production activities.

The concept of benefit-risk analysis is fundamental for the characterization of medical robots. The use of a medical robot is expected to generate a certain benefit, in terms of clinical outcome after a treatment or improvement of the quality of life; benefits could also be related to diagnostic outcomes. This introduces a counterweight to the risks related to the use of the medical robot by the patient, as the final aim is not the execution of a working task, but patient health. The assessment of benefits related to a specific medical device should consider several factors, such as the type of expected benefits, their magnitude, the probability of effectiveness of the medical device, the duration of the effects. A benefit-risk comparison should be then performed, and the results recorded in the risk management file. CEN ISO/TR 24971:2020can be considered as a guide on the application of EN ISO 14971:2020, including a guidance on how to perform a benefit-risk analysis.

The clinical data to support the clinical performance claims can be collected during clinical studies. Good clinical practice for clinical investigations with medical devices is set out in EN ISO 14155.

For active medical devices, the standards from the IEC 60601 series apply. Concerning mechanical hazards associated with moving parts, EN IEC 60601-1, which should be considered as the main

reference, considers the acceptability of the residual risk dependent on the actual necessity of exposure to risk for the intended functionality of the medical electrical equipment and the implementation of risk control measures.

Particular standards from the IEC 60601 series, focused on specific categories of medical electrical equipment, may modify, replace or delete requirements reported in EN IEC 60601-1, as well as adding further basic safety and essential performance requirements. EN IEC 80601-2-78:2020 should be considered for the "Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation" (RACA robots), that are not clearly addressed in the EN IEC 60601-1 or for which interpretation can be complicated. Although a number of tests are specified related to the integrity of the device, no testing procedures are provided concerning the mechanical hazards that may affect the safety of the utilizer directly.

In EN IEC 80601-2-77:2021, which should be considered as a reference for robotically assisted surgical equipment (RASE), it is explicitly specified that RASE are characterized by zero autonomy, being aimed at assisting the surgeon, and, accordingly, could not be considered a medical robot. Likewise, no specific conditions for which this document may be relevant were individuated at the drafting stage. However, its relevance is not excluded on purpose, but limited to the interaction between the robot and the operator.

IEC TR 60601-4-1:2017 widely addresses the concept of "degree of autonomy", providing also a classification method; according to this document, the manufacturer may decide to label a medical electrical equipment or a medical electrical system as a medical robot whenever the definition of "robot" is satisfied.

Other relevant standards are the EN 62304, dealing with software life cycle processes and EN 62366-1, dealing with the safety-related usability requirements for the development of medical devices. In relation to the latter, EN IEC 80601-2-78:2020 introduces the concept of situation awareness into the usability engineering process.

Annex B(informative)
List of test methods provided by standards

A list of test methods related to mechanical hazards in robot applications is reported in Table B.1. The list may not be exhaustive.

Table B.1 — Robot test methods provided in standards related to mechanical hazards

Standard/ Document	Clause, sub-clause or Annex	Type of test	Relevance	
			HRC skill	Robots/Robotic devices
EN ISO 3691-4:2020	Sub-clause 5.2	Tests for detection of persons	Maintain safe distance	Mobile robot, mobile robotic arm
	Sub-clause 5.3	Stability tests	Dynamic stability	Mobile robot, mobile robotic arm
EN ISO 18497:2018	Sub-clause 5.4	Verification of minimum performance of the system perception and safety	Maintain safe distance	Mobile robot, mobile robotic arm (outdoor)
ISO/FDIS 10218-2:2021	Annex N (informative)	Validation of power and force limited collaborative applications by pressure and force measurements	Limit physical interaction energy	Robotic arm
ISO/TR 23482-1:2020	Clause 7	Physical hazard characteristics (for mobile robots)	Limit physical interaction energy	Mobile robot/mobile robotic arm
	Clause 8	Physical hazard characteristics (for restraint-type physical assistance robots)	Limit restraining energy	Robotic arm
	Clause 11	Static stability characteristics	Dynamic stability	Mobile robot/mobile robotic arm
	Clause 12	Dynamic stability characteristics with respect to moving parts (mobile robot)	Dynamic stability	Mobile robot/mobile robotic arm
	Clause 13	Dynamic stability characteristics with respect to travel (for mobile robot)	Dynamic stability	Mobile robot/mobile robotic arm
	Sub-clause 14.2	Test of operation in slippery environments	Dynamic stability	Mobile robot/mobile robotic arm

	Clause 15	Response to safety- related obstacles on the ground (mobile robot)	Maintain safe distance	Mobile robot/mobile robotic arm
ISO 18646-1:2016[a]	Clause 6	Stopping characteristics	Maintain safe distance	Mobile robot/mobile robotic arm
	Clause 7	Maximum slope angle	Dynamic stability	Mobile robot/mobile robotic arm
	Clause 9	Mobility over the sill	Dynamic stability	Mobile robot/mobile robotic arm
ISO 18646-2:2019[a]	Clause 6	Obstacle detection	Maintain safe distance	Mobile robot/mobile robotic arm
	Clause 7	Obstacle avoidance	Maintain safe distance	Mobile robot/mobile robotic arm
ISO 18646-3:2021[1]	Sub-clause 5.3	Grasp strength	Limit physical interaction energy	Gripper
ISO 18646-4:2021[1]	Clause 5	Test method for assistive torque index and lumbar compression reduction	Limit restraining energy	Exoskeleton
[a] Not explicitly safety-related, but potentially relevant				

Annex C(informative)
System-level validation protocol template

In Table C.1, a suitable template for structuring a SLV protocol is shown, indicating clauses, sub-clauses and the relevant information which may be included.

Table C.1 — Structure template and generic contents of a SLV protocol

Clause/ Sub-clause	Contents
1. Introduction	
1.1 General	Purpose of the SLV protocol: objective, scenario, HRC skill. Generic figures of the real scenario and the corresponding real setup.
1.2 Scope and limitation	Profile of the SLV protocol. It can be a table including details of: — HRC skill (e.g., maintain safe distance); — System (robot or robotic device, e.g. robotic arm); — Sub-System (e.g., end-effector); — Domain (possible applicable domain, e.g. manufacturing); — Conditions (main conditions characterizing the SLV protocol, e.g. indoor); — Measurement device(s) (list of measurement devices required for the test).
1.3 Definitions and terms	Definitions used in the document and source (source reference/local to the document)
2. Concept and objectives	
2.1 Hazardous situations	Indication on how to identify, based on the risk assessment, the hazardous situations to be considered for the specific SLV protocol. If relevant, the SLV protocol should suggest to the *SLV protocol user*[a] to indicate the description of state of the robot (position and velocity; if necessary, specified for each axis) preceding the hazardous situation, as identified by the risk assessment and to be reproduced for SLV.
2.2 Target behaviour and metrics of the HRC skill	Indication on the target behaviour and the target metrics relevant for the HRC skill. The target metrics are based on physical and measurable quantities, which are the output variables of the SLV. The values of the target metrics correspond to a system behaviour compliant, from the perspective of the HRC skill, with the required level of risk reduction (whose determination is out of the scope of the SLV protocol). They represent a threshold that the output values of test should not exceed for considering the test trial(s) as passed. The outputs expected from the application of the SLV protocol are figures to measure for computing target metrics or binary variables indicating whether

	a condition is met or not. Relevant physical units for output quantities should be indicated.
3. Conditions	
3.1 General	Indication on the development of a test plan containing all the relevant combination of conditions affecting the hazardous situation.
3.2 System	Description of robot system-related conditions which can change for the hazardous situation and which have a significant impact on the test results and indication for the *SLV protocol user*[a] on how to report these details.
3.3 Environment	Environmental conditions which have a significant influence on the validation results (e.g., inclination or surface conditions) and indication for the *SLV protocol user*[a] on how to report these details.
3.4 Miscellaneous	Description of possible other relevant conditions and indication for the *SLV protocol user*[a] on how to report these details (optional).
4. Test setup	
4.1 Equipment	Description of the sensors (e.g., load cell) and other devices (e.g., photo sensors) required for the test. Commercially available sensor types should not be specifically mentioned in the SLV protocol, but indication for the SLV protocol user[a] on how to report these details should be provided.
4.2 Method	Instructions for arranging the sensors and the system within the test environment. Drawings supporting the description could be included. If relevant, instructions for recording, logging, and pre-processing (filtering, offset compensation) sensor data should be also included.
5. Procedure	
5.1 Test plan	Instructions for creating the test plan, with variation of the identified test conditions in a systematic manner.
5.2 Preparation	Instructions to prepare each part of the setup and all conditions with a significant influence on the target metrics, including: — Test arrangement; — System conditions; — Environmental conditions.
5.3 Test Execution	Test procedures to apply.
5.4 Data analysis	Instructions for interpreting the results, e.g. pass/no-pass, interval analysis, etc.
5.5 Report	Instructions for creating the report using an annexed form.
6. Bibliography	Relevant standards and other references
7. Annexes	Templates for reporting and eventual further relevant information.
[a] *SLV protocol user* refers to the person or group of persons conducting the SLV by using a SLV protocol.	

Annex D(informative)
Example of SLV protocol: Test mobile platform to maintain a separation distance

D.1 Introduction

D.1.1 General

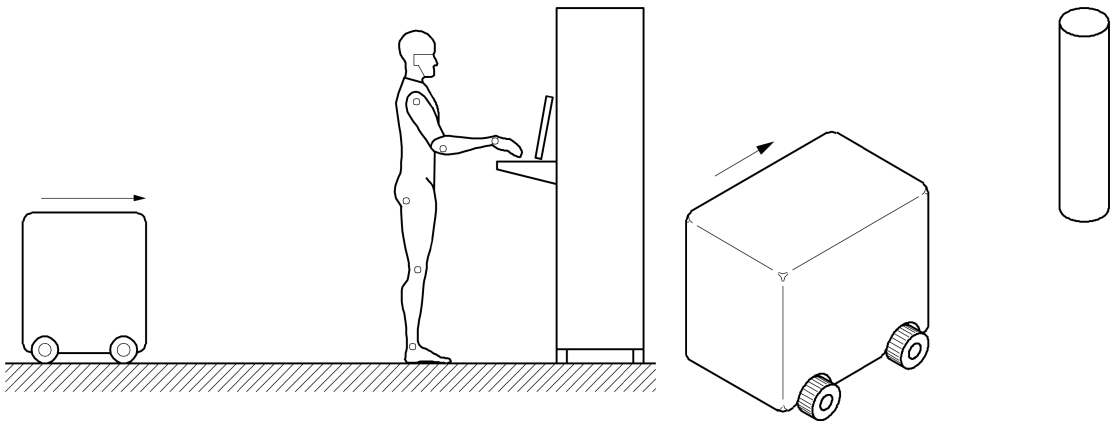
NOTE This Annex is aimed at providing an example of SLV protocol, drafted considering the HRC skill "maintain safe distance" and a mobile robot used in an indoor application as robot device. The SLV protocol example provides instructions for performing the SLV. Referring to existing relevant standards (i.e. EN ISO 3691-4:2020), the SLV protocol targets a wide series of HRC application. The SLV protocol is not aimed at substituting the verification of safety requirements and/or protective measures related to the proper functioning of robot safety functions (i.e. the verification procedure related to industrial trucks reported in EN ISO 3691-4:2020), but to check the whole HRC application achieves the HRC skill.

This SLV protocol describes how to test the ability of a mobile robot, able to navigate under its own control, to maintain a safety distance with respect to a static obstacle, i.e. a stationary human on its path. This SLV protocol is applicable to all mobile robots that have collision avoidance functionality realized by non-contact sensors to operate a protective stop, typically operating in indoor environments.

It is checked that the robot stops and that the minimal distance between an operator and the robot after its full stop remains above a predefined distance (see Figure D.1.

This SLV protocol is specific for stationary operator detection and avoidance in the robot's navigation space.

Example: A mobile robot operating in a hospital performs a navigation task. It operates in a "workspace" with objects, humans, and possibly other mobile robots. A hospital worker stands in the way of the robot's path. In that situation, unintended collisions between the robot and the worker should be avoided.



a) risk scenario **b) general test setup**

Figure D.1 — Risk scenario and general test setup for the proposed example.

D.1.2 Scope and limitation

This SLV protocol is specifically limited to profile reported in Table D.1.

Table D.1 — Profile of the SLV protocol "Test mobile platform to maintain a separation distance"

HRC skill	Maintain Safe Distance
System	Mobile Robot
Sub-System	Optional. Example: a trailer In case of a robotic arm mounted on the mobile robot, a SLV protocol dedicated to a mobile robotic arm should be considered.
Domain	manufacturing, public, consumer, logistics
Environment	Indoor: factory, warehouse, indoor public place, non-medical professional indoor environments; Outdoor: warehouse; The safety-related object/obstacle is fixed (no dynamic/moving obstacles).
Measurement Device(s)	A distance measurement device, a test piece for simulating human body parts, ground markers (optional)

D.1.3 Definitions and Terms

D.1.3.1 Collision (source: ISO 19649:2017)

Dynamic contact resulting in momentum exchange.

D.1.3.2 Obstacle avoidance (source: ISO 19649:2017)

Preventing interference, such as approaching, contacting or collision, with obstacles by detecting them with external state sensors and adjusting trajectory planning.

D.1.3.3 Collision avoidance (source: ISO 19649:2017)

Preventing collision using external state sensors and reacting accordingly.

D.1.3.4 Mobile robot (adapted from: ISO 19649:2017)

Robot able to travel under its own control.

NOTE For the purposes of this SLV protocol, the definition is restricted to a mobile robot without manipulators.

D.2 Concept and Objectives

D.2.1 Hazardous Situation

The test simulates a risk of collision of the robot, using an obstacle that mimics the human body. The resulting clearance is measured with a distance measurement device. During the test, the robot should operate under the same conditions as it would in a real application, considering whether the scenario falls under the intended use or foreseeable misuse.

The objective of the test is the SLV of the HRC application from the perspective of the HRC skill "maintain safe distance", by checking that the robot does not exceed the applicable minimum distance limit value, which should be specified in the risk assessment.

The risk assessment specifies under which hazardous situations the robot may operate. The test measurements determines whether the HRC skill is achieved or not.

D.2.2 Target Behaviour and Metrics of the HRC skill

The relevant target behaviour from the perspective of the HRC skill is to maintain a minimum distance between the mobile robot and the safety-related object. The distance should not be less than a limit specified in the risk assessment.

For this SLV protocol, the output is:

— The distance after a full stop of the robot between the robot itself and the safety-related object [m].

The target metric is the limit value determined during the risk assessment:

— The minimum acceptable distance between the robot and the safety-related object [m].

The target metric may vary depending on size and weight of the obstacle. The values of the target metric for each test should be reported by using the report table in the Report form in D.7.

NOTE To take into account possible movement of the worker, the required minimum stopping distance could be increased by an additional term, representing the distance possibly covered by the worker and evaluated as $S_h\left[m\right] = 1.6\left[\frac{m}{s}\right] \times T\left[s\right]$, where T is the overall stopping time in seconds (time interval between obstacle detection and the termination of the hazardous machine function). Refer to EN ISO 13855 for further details.

NOTE If the mobile robot subsystem and/or expected payload feature geometries exceeding the footprint of the robot, then the relevant distance should be added to the required target metric.

D.3 Conditions

D.3.1 General

In case the conditions under which the hazardous situation may occur can change, a test plan containing all their reasonable and relevant combinations should be developed. The applied HRC skill is tested for each relevant combination of this list. Therefore, it is important to know the significant conditions that influence the target metric e.g., high speed and load.

D.3.2 System

The “system” is identified by the type of mobile robot with its payload and, if present, the subsystem(s). The category of subsystems comprehends a variety of tools and additional functionalities that can be installed onto the mobile robot. The subsystem can be a mechanical, electro-mechanical or robotic device working in coordination with the mobile robot (robotic arms are excluded in this SLV protocol). Also trailers eventually drawn by the mobile robot are to be considered subsystems and described.

The task-specific conditions should be previously identified in the risk assessment. The form in D.7 can be used to report the system composition for each single test. It should be noted that subsystem(s), payload and their configuration may affect the risk assessment.

The following system-related conditions influence the target values:

— mobile robot velocity [mm/s] (identified in the risk assessment);

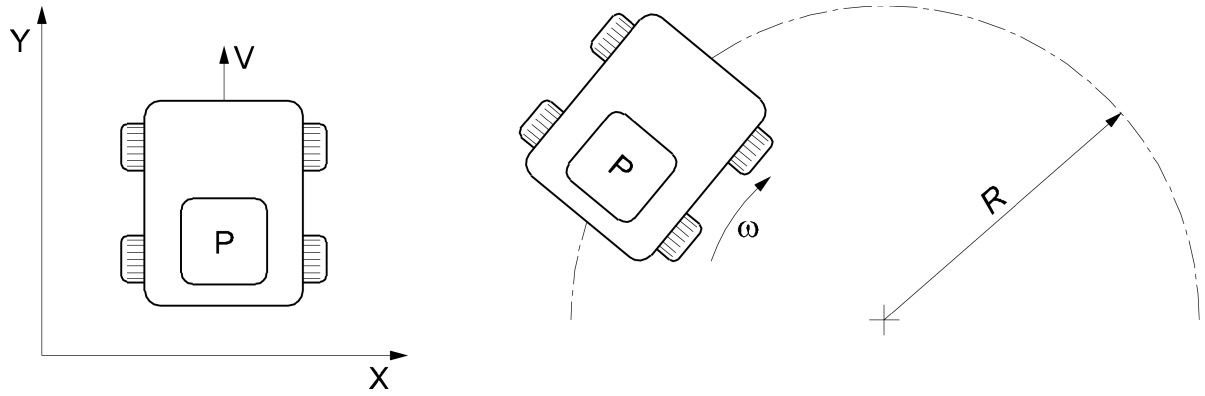
— mobile robot payload [kg] (identified in the risk assessment; 110% of actual payload, as per EN ISO 3691-4:2020 should be considered).

System condition(s) relevant for testing should be considered and reported (e.g. loaded, unloaded, lift height, slope, turn, forward, backward, floor/ground slope), in combination with mobile robot

predetermined parameters in those case conditions (e.g. emergency braking deceleration, speed, controlled acceleration, deceleration).

Besides the configuration of the robot system, the trajectory of the robot prior to the stop also has a significant influence on the output target. The following parameters describe the robot state:

— Direction and magnitude of mobile robot velocity (linear and/or rotational, see Figure D.2).



a) linear velocity **b) angular velocity**

Key

V linear velocity
P payload
ω angular velocity
R radius of curvature

Figure D.2 — Velocity of the mobile robot

These conditions are part of the robot path, which is technically a time dependent sequence of states. The point of interest for the test is the point along the robot path at which the distance to the safety-related object is minimum. The risk assessment should clarify the exact moment and position of this point. Therefore, the risk assessment is the primary source to identify the robot state for the test.

D.3.3 Environment

The following environmental conditions may have an influence on the SLV:

— Adhesion properties of the navigation floor;

— Floor/ground slope [%];

— Illuminance level [lux];

— Any environmental conditions influencing the sensor(s) used for detection.

Since the environment conditions may have an ineligible influence on the target metric, it is worth running the validation tests under the same environmental conditions which are expected during actual operations.

D.3.4 Miscellaneous

Other relevant conditions are:

— Surface of the mobile robot that will come the closest to the test piece;

— Endangered body parts (parts of the test piece which the robot can affect);

— Testing route features (length and width of the navigation area, transversal position of the mobile robot).

D.4 Setup

D.4.1 Equipment

According to the target metric, it is necessary to measure the distance between the mobile robot and the test piece collision point. The following instruments are required to measure the target metric:

— An accurate device for distance measurement (e.g. a laser meter with error below 5%)

Variants of this SLV protocol may be based on the use of a different type of distance sensor or a motion tracking system.

The test piece is an object with surface condition and dimensions that simulates body parts that the robot is likely to encounter under the projected conditions of use. EN ISO 3691-4:2020 reports suitable dimensions for cylindrical test pieces to represent the leg of a standing human or the torso of a lying human.

D.4.2 Method

This test measures the distance between a robot and a simulated safety-related object at the moment the robot finishes a protective stop.

The procedure consists of three steps: 1) setup, 2) performing the test with the mobile robot moving, and 3) measuring the distance when the mobile robot has stopped. This test requires a distance measuring device, a defined travel path, and test pieces.

D.5 Procedure

D.5.1 Test Plan

The test plan is a summary of all situations identified as hazardous in the risk assessment. Therefore, the test plan provides a detailed summary which tests are necessary for the considered SLV.

All combinations of the conditions introduced above that are applicable and may change in the considered situation result in a list of concrete test cases. It is suggested to prepare the list before beginning the tests. Sub-clauses D.5.2 to D.5.5 should be applied for each test case and run each test at least three times.

D.5.2 Preparation

D.5.2.1 General

Before executing a concrete test from the test plan, it is necessary to prepare the setup and the conditions properly. The following sections give instruction to prepare each part of the setup and all conditions with a significant influence on the target metric.

D.5.2.2 Test arrangement

The defined travel path should be large enough to enable the robot to accelerate up to the normal operating speed (as defined in the risk assessment), i.e. the *cruise speed* (see Figure D.3). The dimensions of the cylindrical test piece should be chosen considering the actual body part to be considered for the SLV (e.g., to simulate a lying torso or the leg of a standing human, the indications reported in EN ISO 3691-

4:2020 can be considered). Each case of the test plan is related to a particular orientation of the mobile robot with regard to the object.

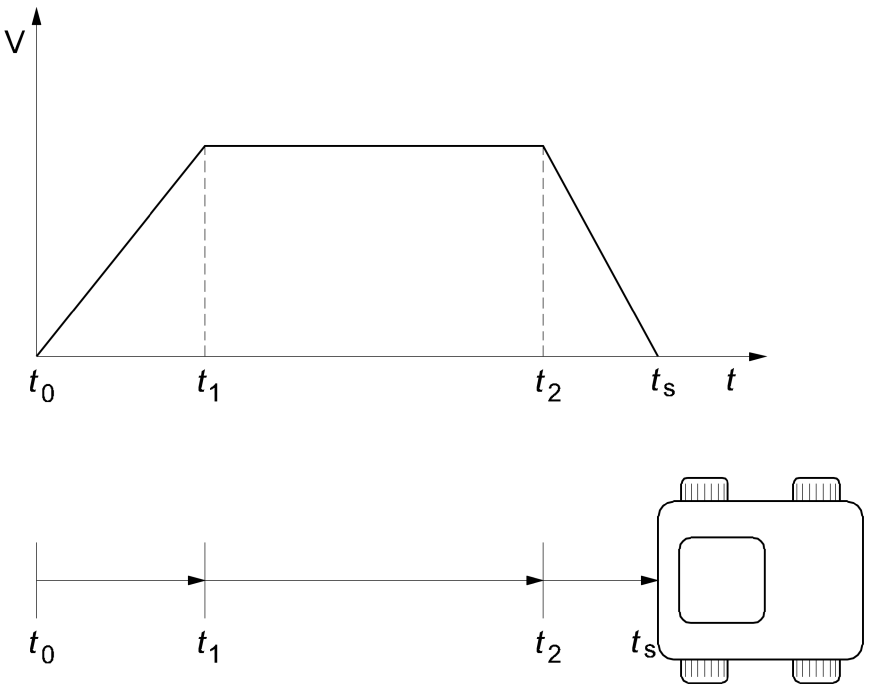


Figure D.3 — An acceleration time t_a, is followed by a cruise time t_c, a braking time t_b, and a full stop at t_s

D.5.2.3 System Conditions

The SLV protocol user should configure the robot in the exact way that it will run in the application. This includes at least the following steps:

— the mobile robot should be switched on one hour before beginning the tests (warm-up phase);

— the mobile robot should be configured with its payload and any sub-systems in accordance with the real working conditions to be tested;

— the program containing all movements and actions the robot will execute in the application should be installed;

— all available safety-functions should be configured.

NOTE If the mobile robot has no safety functions to monitor its states (such as platform speed), all tests should be performed at maximum speed, even if this speed is not required for the application.

The following instructions are related to the conditions which may change for the different use conditions, as identified in the risk assessment.

— Robot velocity;

— Payload (ensuring that no parts can fall off during the test);

— The parameter values of the applied safety functions should be adjusted in accordance to the values specified for the test case.

D.5.2.4 Environmental Conditions

The tests should be performed on the usual mobile robot operating ground, which should be identified in the test plan, as well as with the same level of illumination. Furthermore, the relevant features of the navigation environment (especially those affecting sensor detection) should be as similar as possible to the real use scenario

D.5.3 Test Execution

The following test procedure should be applied for each specified test case separately. It should be ensured that the proper speed set-point and proper orientation of the mobile robot with respect to the safety-related object are configured before running a test.

1) The robot is moved slowly to the initial start position and orientation point, on the proper ground with chosen slope. A position from which the robot has enough space for accelerating to desired speed before reaching the obstacle detection area should be used. The program is then paused with the robot in start position.

2) Speed should be configured according to the real scenario.

3) The test situation may be recorded by taking a picture (optional).

4) The mobile robot autonomous navigation is started.

5) After the complete mobile robot stop (after the object detection), the minimum distance between the mobile robot and the object is measured (see Figure D.4).

6) The final configuration may be recorded by taking a picture (optional).

The test should be repeated at least three times for each risk scenario and identified possible combination of conditions.

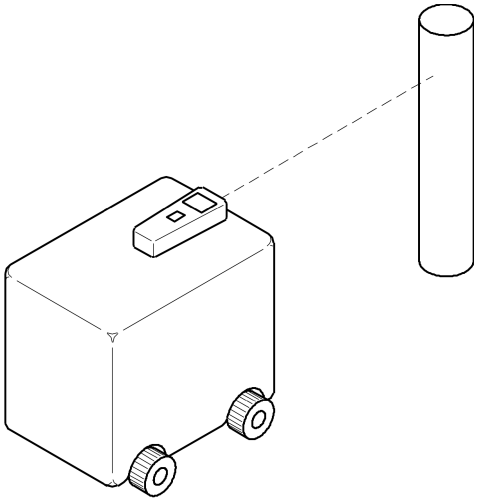


Figure D.4 — Measurement of the distance after the stop of the mobile robot

D.5.4 Data Analysis

The test can be considered successful if the maximum value acquired in the three tests does not exceed the minimum distance limit value identified in the risk assessment. In case of fail, it is recommended to modify the robot program (for instance reducing the speed) in the actual task and to start over with the test process. Other options could be a modification of the mobile robot safety configuration. The test configuration leading to successful testing should be then considered as a modification of the real operating parameters.

D.5.5 Report

The form in D.7 may be used to report all conditions and results of the tests. Once the SLV is completed, the forms can be added to the risk assessment documentation, proving the effectiveness of the robot system concerning the HRC skill “maintain safe distance” in the given scenario.

D.6 Bibliography

[D.1] ISO 8373:2021, Robots and robotic devices - Vocabulary

[D.2] ISO/DIS 10218-1.2:2021, Robotics – Safety requirements – Part 1: Industrial robots

[D.3] ISO/FDIS 10218-2:2021, Robotics– Safety requirements– Part 2: Industrial robot systems, robot applications and robot cells

[D.4] EN ISO 3691-4:2020, Industrial trucks - Safety requirements and verification - Part 4: Driverless industrial trucks and their systems

[D.5] EN ISO 13857, Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs

[D.6] ISO 19649:2017, Mobile robots — Vocabulary

[D.7]EN ISO 13855, Safety of machinery — Positioning of safeguards with respect to the approach speeds of parts of the human body.

D.7 Report Form

D.7.1 General

Description of robot system under validation			
Test date		ID of tester:	
Test ID		Hazard ID	
Photo			

D.7.2 System and related conditions

Mobile robot	
Type of mobile robot	
Manufacturer	
Model + Serial Number	

System Configuration			
Control Software			
Footprint on the ground and dimensions (picture or drawing, including eventual subsystems)			
Payload			
Type and shape			
Position on the robot and dimensions (picture or drawing)			
Mass [kg]			
Subsystem			
Type of system			
Manufacturer			
Model			
System Configuration			
Control Software (if any)			
System state			
Nominal mobile robot velocity	**Absolute**	**X**	**Y**
Linear velocity [mm/s]			
Angular velocity [rad/s]			
Turning radius (if available) [mm]			

D.7.3 Conditions: environment

Type of floor and adhesion properties	
Floor/ground slope [%]	
Illuminance level [lux]	
Environmental conditions possibly influencing sensor acquisitions	

D.7.4 Conditions: miscellaneous

Closest Area to Safety-Related Object (on robot structure)	
Location	
Picture (if relevant)	
Endangered parts	
Type of obstacle (i.e. worker or object)	
Part (e.g. a leg)	
Testing route features	
Length [m]	
Width [m]	
Mobile robot transversal position	

D.7.5 Target metrics

Obstacle	
Minimum distance [m]	

D.7.6 Setup

Sensor	
Type and manufacturer	
Working Range [m]	
Accuracy in test conditions [mm]	
Resolution [mm]	
Test piece	
Type and shape	
Dimensions	
Initial position in the test route	
Source (if relevant, e.g. a standard)	

D.7.7 Test Results

Test ID			
	Trial 1	**Trial 2**	**Trial 3**
Measured distance [mm]			
Minimum measured distance [mm]			
Minimum target distance			
Test result [Pass/Fail]			

D.7.8 Final information about the test

Date of testing	
Name of tester	
Overall conclusion	
Signature	

Annex E(informative)
Example of SLV protocol: Test manipulator in shared human-robot control to prevent spatial overreaching for the utilizer

E.1 Introduction

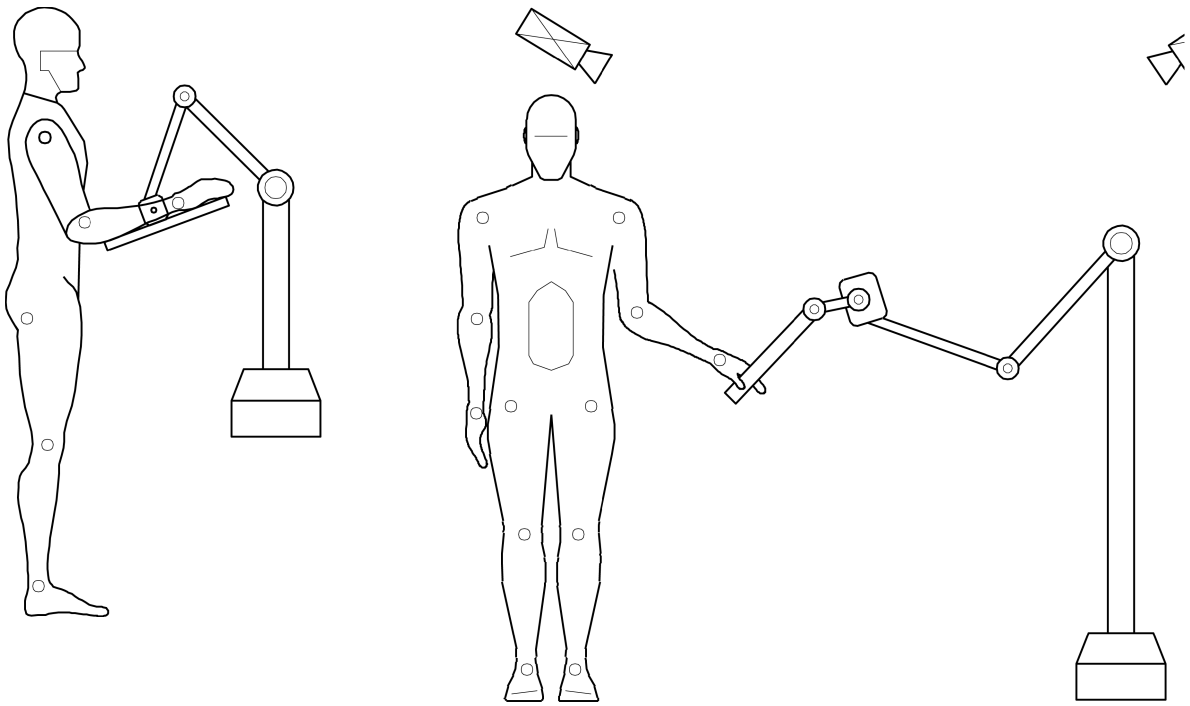
E.1.1 General

NOTE The Annex is aimed at providing an example of SLV protocol, drafted considering the HRC skill "limit range of movement" and a robotic arm used in hand-guiding or human-robot shared control. The SLV protocol example provides instructions for performing the SLV, along with some examples on how to report test data and acquired values.

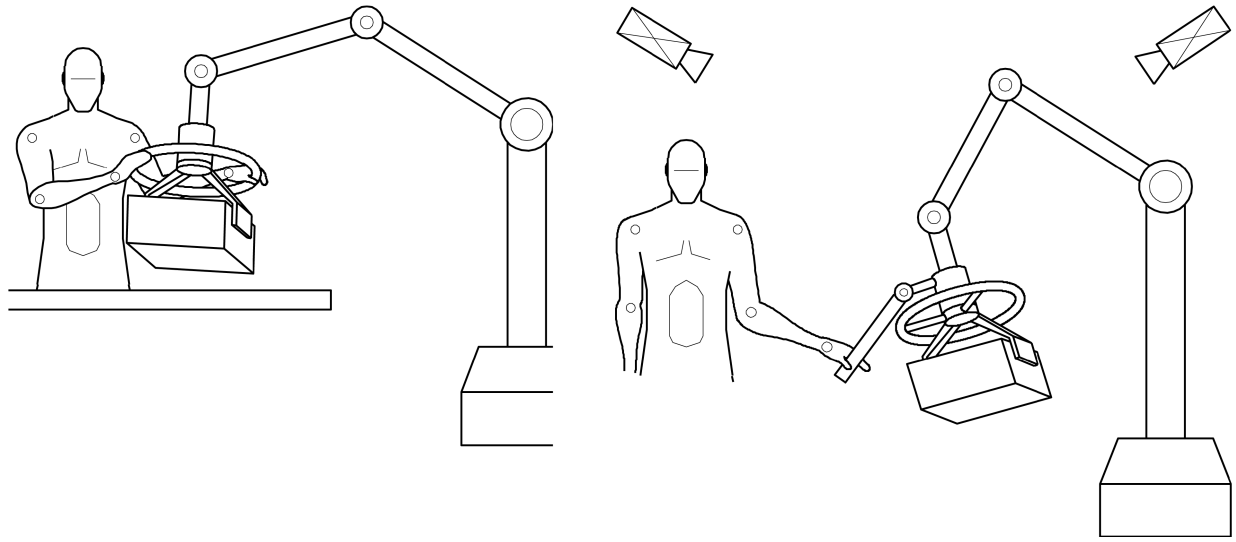
The purpose of this SLV protocol is the SLV, from the perspective of the HRC skill "limiting range of movement", of a robotic arm used as a RACA robot or in a hand guiding collaborative application by restricting spatial range of motion for its end-effector, as well as any other part of the robot system (e.g. soft axis and space limiting safety function or mechanical axis limiting devices as per ISO/DIS 10218-1.2:2021), in order to avoid physical damage to the person connected to the robot system.

The primary hazardous situation considered is an over stretching of the utilizer limbs, where the distance between a proximal and a distal joint is too large. A secondary hazardous situation considered in this SLV protocol is that parts of a robotic system may collide with parts of the body of the utilizer.

Figure E.1 reports two real cases in which this protocol may be relevant and the related general test setup configuration.



a) robotic arm in a rehabilitation application **b) test setup for the rehabilitation application**



c) a hand-guiding collaborative application **d) test setup for the collaborative application**

Figure E.1 —Possible applications of the SLV protocol and related test setups

E.1.2 Scope and limitation

This SLV protocol is specifically limited to the profile reported in Table E.1.

Table E.1 —Profile of the SLV protocol

HRC skill	Limit range of movement
System	Robotic arm
Sub-System	Mounting platform for the robotic arm that stabilizes the position of the robot relative to the body of the utilizer
Domain	Manufacturing, Healthcare
Conditions	3D movement Hand-guiding or Human/robot shared control (active movement of the human)
Measurement Device(s)	Optoelectronic measurement system/motion tracking system

E.1.3 Definitions and Terms

E.1.3.1 Active movement

A movement of parts of a human body, produced by muscles of that human, not by external forces applied to these parts of the human body.

E.1.3.2 Emergency stop (adapted from the definitions in: ISO 12100:2010 and EN IEC 80601-2-78:2020)

Manually initiated interruption of operation intended to stop the robot to avert arising or reduce existing hazards to persons, damage to machinery or to work in progress.

E.1.3.3 End-effector (source: ISO 8373:2021)

Device specifically designed for attachment to the mechanical interface to enable the robot to perform its task. For RACA robots this is also described as the (actuated) applied part (EN IEC 80601-2-78:2020).

E.1.3.4 Human Tester

Qualified person who executes the test.

E.1.3.5 Monitored point

Either a point on the robot or a point in space in relation to a specific point on the robot. For example, if the monitored point intended to match the utilizer's hand, it might be defined as a point in a fixed distance from the upper limb splint or from the end effector.

E.1.3.6 Marker

Active or passive spatial element used by an optoelectronic measurement system to determine a spatial position within a predefined volume.

E.1.3.7 Motion tracking system

A system used to detect spatial coordinates of objects in a restricted volume as a function of time.

E.1.3.8 Optoelectronic measurement system

A system used to detect spatial coordinates of objects in a restricted volume by camera-like sensors.

E.1.3.9 Overreaching

A movement that results in the monitored point exceeding the range of motion. It can be harmful to the utilizer as the movement can exert an excessive strain on joints.

E.1.3.10 Passive movement

A movement resulting from an external force working on parts of a human body (e.g. limb), without any voluntary contribution to that motion by that human. Accordingly, the passive aspect is viewed from the human perspective.

E.1.3.11 Predefined path

A movement trajectory that is specified with more parameters, possibly a set of spatial coordinates.

E.1.3.12 Protective stop (adapted from the definitions in: ISO/FDIS 10218-2:2021 and EN IEC 80601-2-78:2020)

Type of interruption of operation that causes a cessation of motion for protective and safeguarding or basic safety and essential performance purposes and which retains the information of the state of the robot to facilitate a restart.

E.1.3.13 RACA robot (source: EN IEC 80601-2-78:2020)

Medical robot intended to perform Rehabilitation, Assessment, Compensation and Alleviation robot, comprising an actuated applied part.

E.1.3.14 Range of Motion (ROM)

A combination of linear and angular distance that a defined monitored point may move in relation to a defined reference point. The monitored point can be either a point on the robot, or a point on the body of the utilizer defined relatively to a point on the robot. The ROM can be limited to a straight line (one-dimensional ROM), a plane (two-dimensional ROM) or a space (three-dimensional ROM) in any shape. Has to be defined in relation to a reference point.

E.1.3.15 Reference point

Either a point on the robot or defined as a point in space in relation to a specific point on the robot. For example, if the reference point should represent the expected location of the utilizer's shoulder joint centre, it might be set at a fixed distance from the robot surface. Please note that the reference point has to be a spatial location, which keeps a known position in relation to proximal parts of the robot.

E.1.3.16 Rehabilitation robot

RACA robot used in rehabilitation.

E.1.3.17 Single fault condition, SFC (adapted from: EN IEC 60601-1)

A condition of a robot system in which a single means for reducing a risk is defective or a single abnormal condition is present.

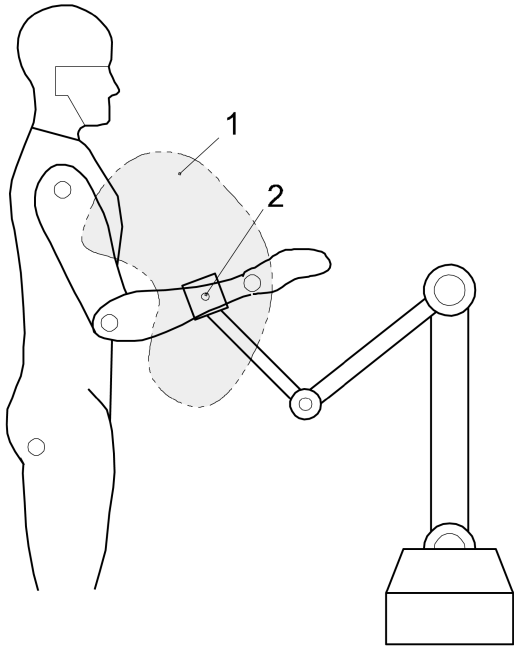
E.1.3.18 Target point

Location of a point in a certain volume, relative to the reference point, the robot will be instructed to move the monitored point to.

E.2 Concept and Objectives

E.2.1 Hazardous Situations

During the rehabilitation or working task, the robot system will be either attached to a human, in order to mobilize a limb or to assist the use of the impaired limb in daily life, or equipped with a hand-guiding control device (hand-guided controls in ISO/FDIS 10218-2:2021). Based on the initiated movement by the utilizer, the robot will support that movement with a support level that can be set either during installation or by a therapist to suit the required levels during a rehabilitation session. Based on anthropometric properties and physical restraints of the human as well as the required movement types, some specific boundaries to the movements of the robotic arm are likely to be set. The distance between a proximal joint centre (e.g. shoulder or hip) and a distal joint centre (e.g. wrist or ankle) should stay indeed within a certain area (see Figure E.2). Likewise, in a hand-guided collaborative robotics application, safety-rated soft axis and space limiting function may be used to limit the range of motion for safety and ergonomic purposes.



Key

1 ROM volume

2 end-effector point

Figure E.2 — Example of an application scenario (in a rehabilitation task the utilizer may also be seated)

The hazardous situations considered in this SLV protocol are:

— over-stretching of the human joints/limbs, where the distance between a proximal and a distal joint is too large;

— a link of the robot moving through a space where human's body parts are located.

E.2.2 Target Behaviour and Metrics of the HRC skill

The target behaviour relevant from the perspective of the HRC skill concerns whether the robot system keeps the relative displacement between a reference point and the monitored point within the specified ROM.

The movements of a robot system performing an active rehabilitation task or a hand-guiding application are mainly defined by the input of the human and the shared control settings for this robot, i.e. the range of motion restrictions and possible support levels set for the robot controller. The movements carried out can usually be described by a linear path between two points or, more likely, a more complex trajectory between two points.

The shape of the ROM for which this test needs to be performed has to be based on the use specifications of the robot, so it represents a proper normal use situation. During the definition of a representative ROM description for the tests, it should be considered that:

— the ROM can take any shape and does not have to be symmetrical to the reference point;

— the shape and size of the volume will have a large impact on the validation results. Therefore, a matching description of the ROM volume used by the robot should be used during data analysis.

The target metrics are based on physical and measurable quantities. These quantities are the output variables for the validation. The values of the target metrics indicate if the validated HRC skill is effective enough to achieve the specified level of risk reduction. They represent a threshold that the output values of the test should not exceed for considering the test as passed. These values for the ROM in a 3D space can be variable during intended use; for example, it may be determined by a therapist for the individual utilizer in a rehabilitation setting. Therefore, the systems' ability to keep the end-point within the set safe area needs to be validated using different settings for both the endpoint setting and the area where the other parts of the body would be.

It may also be possible that other parts of the robot system move through spatial areas where other body parts of the human being are. It should be observed during this test whether parts of the robot system are kept clear from other body parts of the utilizer.

For this SLV protocol, the target metrics are defined as follows:

— Does the monitored point move outside the defined ROM? [YES/NO]

— Does any part of the robot enter an area where it may collide with any part of the human body? [YES/NO]

E.3 Conditions

E.3.1 General

In case the conditions under which the hazardous situation may occur can change, a test plan containing all their reasonable and relevant combinations should be developed. The test should be performed for each relevant combination of this list. Therefore, it is important to know the significant conditions that influence the target metric.

E.3.2 System

The term system refers to the robot system consisting of:

— a robotic arm, that is intended to move, along with a body part, within a specified workspace (ROM);

— a base the robot is mounted on (which, in case of a RACA robot, is also connected to the support base for the utilizer);

— optionally, a cuff or splint attached to the end-effector of the robotic arm to fixate a single body part;

— optionally, a hand-guiding control device;

— optionally, a tool used as end-effector and, if relevant, a payload.

The SLV protocol applies to the complete system as it is normally used. This can include an applied part connected to the end-effector of the robot, e.g. a splint, which, in normal use, is connected to a body part of the utilizer with the intention to move that body part and which movements are predictable in relation to the motions of the robotic arm. Besides normal use conditions, it may be considered, depending on the requirements of the specific application, to perform the tests in relevant SFCs which may influence the SLV, such as:

— when an emergency stop or a protective stop is initiated;

— when the payload is released accidentally;

— a SFC where an invalid sensor data that may influence the controller behaviour or the applied risk reduction measure or risk control measure;

— a SFC where failure of an actuator that may influence the behaviour of the controller or the risk reduction measure or risk control measure.

During the risk assessment, special attention should be paid to properly identify relevant SFCs.

E.3.3 Environment

Environmental conditions may influence the SLV, depending on the implementation. When applicable, the validation tests should be performed under various environmental conditions, that are considered normal use conditions and that may have an influence on the SLV. Examples of this could be:

— inclination angle of the robot's base (e.g. when the robotic arm is mounted on a mobile robot or mobile support/device);

— externally induced motions/accelerations of the total combination of robot system and the human (e.g. when both the robot system and the human are on the same moving platform e.g. wheelchair), since these may have a significant influence on the inertia of the entire system.

E.4 Setup

E.4.1 Equipment

For the SLV under consideration, a motion tracking system is used. With this system, it is possible to measure spatial coordinates of multiple markers over time.

The required accuracy of the motion tracking is determined by the required accuracy of the measurements that is derived from the risk assessment. As a general guideline, an acceptable accuracy may be about 10 mm, but other values can be acceptable if based on a proper risk assessment.

The acquisition rate used by the motion tracking system should be at least a factor 10 higher than the highest expected frequency component of principal motion of the robot during the test. For normal human movements, an acquisition rate of 100 Hz may suffice.

E.4.2 Method

For the check of the ROM, a motion tracking system is used to measure spatial coordinates of multiple "markers". Using these markers, the spatial coordinates of objects can be directly measured or derived. The robot system should be positioned in such a manner that all robot movements can be properly detected with the measurement system (see Figure E.3).

Markers will be placed on the robot system at the monitored point and the reference point or, should this not be feasible, markers should be placed at locations on the robot system from which, during any movement of this robot, the location of the monitored point and the reference point can be reconstructed.

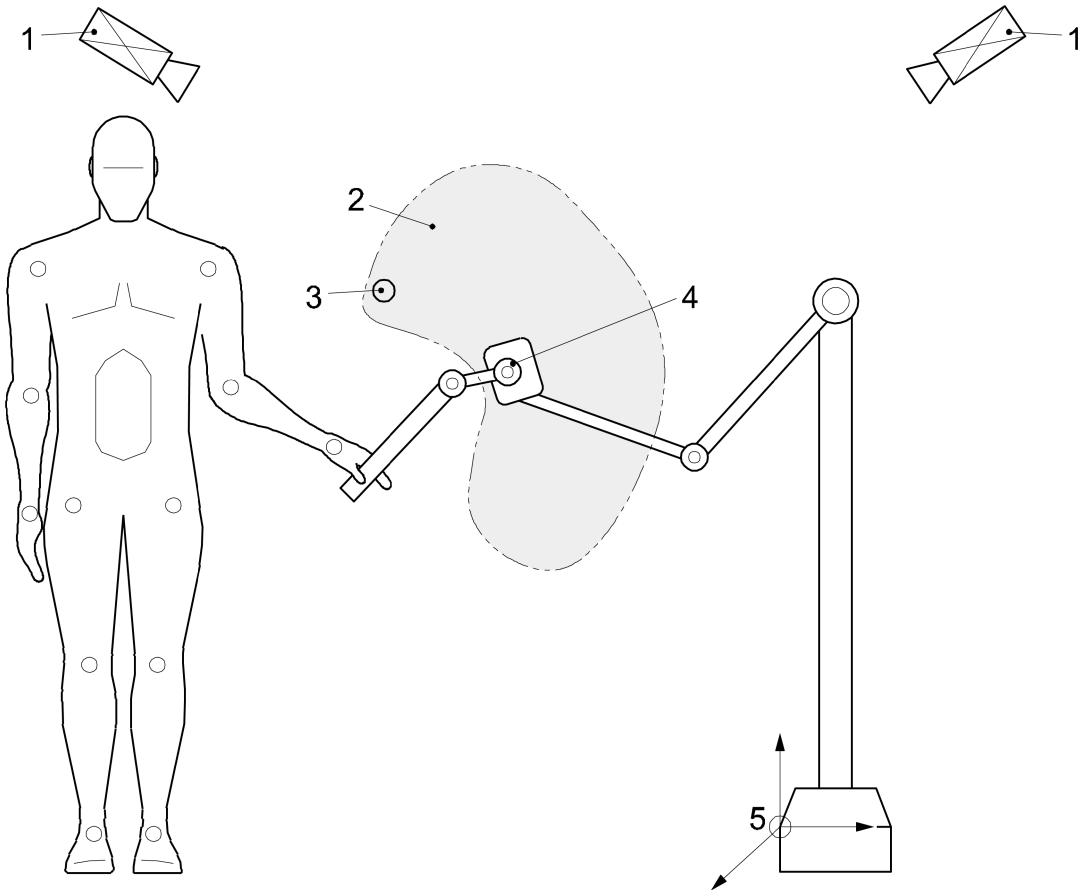
Since the robotic arm motion control depends on the movements of the utilizer, when safely possible, the movements can be applied by a human tester. However, a proper analysis should be performed on the entire test setup before the decision can be made that the test movements can be performed by a human tester. The main measures to ensure the safety of the human tester can be:

— possibility for the human tester to remain out of reach of the robotic arm during the test;

— during the execution of the test, use of a 3-stage enabling switch by the human tester, which should be connected to the robot system as an emergency stop so the robot can be stopped immediately when a dangerous situation would arise.

After data acquisition, the data has to be processed to determine whether during the test the monitored point was located outside the predefined ROM volume. The measured location data can be filtered to remove high frequency measurement inaccuracies, but this filter should not use a cut-off frequency lower than 5 times the highest expected frequency component of the principal motion of the robot during the test. For normal human movements a cut-off frequency for filtering the marker data of about 10Hz, using a zero lag filter, may be sufficient.

The shape and size of the volume will have a large impact on the test results. Therefore, a clear definition of the ROM volume used by the robot system during the tests should be available and used during data analysis.



Key

1 cameras for marker tracking
2 ROM volume
3 target point
4 end-effector point
5 reference point

Figure E.3 — General test arrangement with a 3D motion tracking system and a human tester

E.5 Procedure

E.5.1 Test Plan

The test plan should cover all situations, which the risk assessment identified as hazardous due to moving the monitored point outside a predefined ROM volume, including all combinations of applicable

conditions. Therefore, the test plan provides a detailed summary of the necessary tests for the SLV under consideration.

The test plan should at least cover the motion paths identified by the risk assessment as potentially hazardous. This means that by moving the arm of the robot system, it should be provoked to move the monitored point into or through a spatial area that is outside of the predefined ROM volume. The purpose of the test is to validate whether the robot system exceeds this volume or not.

The SLV protocol should consider the following conditions.

— For defining the motion trajectories, motions should at least cover:

  — trajectories of the monitored point to locations outside the specified ROM;

  — trajectories of the monitored point to either locations inside or outside of the specified ROM volume, where a part of the path could cross an area outside of the specified ROM volume, should this be the shortest route;

  — trajectories where parts of the robot system may collide with parts of the utilizer's body during normal operation.

— Tests should be run as much as possible at maximum speed with specified maximum allowed payload for the robot system and under otherwise normal use conditions. This load should be positioned in such a way that its centre of mass would be close to the end-effector of the robot, unless another location is more conform to normal use conditions.

— If ROM settings can be modified by the utilizer, these tests have to be performed with a selection of different ROM settings that are a proper representation of the range of different settings.

— If applicable, these tests also have to be performed under system inclinations that may affect the SLV.

— If applicable, the tests mentioned above should be repeated also under SFCs that may have an effect on the SLV.

E.5.2 Preparation

E.5.2.1 General

Before executing a particular test from the test plan, it is necessary to prepare the setup and the conditions properly. The following sections give instructions to prepare each part of the setup and all conditions with a significant influence on the target metrics.

E.5.2.2 Test arrangement

For preparing the validation setup:

— the environmental conditions such as lighting should be appropriate for the used measurement technique;

— the motion tracking system should be calibrated as described in its user manual, or existing calibration should be checked. The calibration accuracy should meet the required accuracy.

— the robot system should be positioned within the capture range of the motion tracking (e.g. 3D electro-optical measurement) system.

The reference point and monitored point as defined by target behaviour need to be tracked by the 3D motion tracking system. The tracking of the reference point can be achieved by one of the following:

— by placing a marker on a stand so that it is positioned in the reference point;

— by defining points in the environment, either on the robot system or in the room, from which the location of the reference point can be accurately reconstructed;

— by reconstructing the reference point from marker points placed on the robot system (this has to be done if the reference point can move due to movements of the robot).

Optionally, for the detection of the possibility of undesired collisions with other body parts by any part of the robot:

— an object representing the relevant body parts can be positioned to easily detect potential, undesired contact between the robot system and a human. Make sure these objects do not obstruct visibility of relevant optical markers.

The tracking of the monitored point can be achieved in a number of ways, e.g.:

— by attaching a marker directly on the robot system, if the monitored point is defined as a point on the robot system;

— if the monitored point is not defined as a point on the robot system, either by attaching a marker on a clamp or dummy limb segment attached to the robot system, or by defining points on the robotic arm from which the location of the monitored point can be accurately reconstructed.

E.5.2.3 System Conditions

The system composition for each single test should be reported. In E.7 a suitable form is provided.

The specific use conditions of the HRC application may envisage a “free” (or, equivalently, “transparent”) mode, in which the robot system only supports its own weight/inertia, and/or a “shared control” mode, in which robot control contributes to robot movements, based on utilizer inputs.

— If possible, tests should be performed with the device in “transparent” mode. The test should be performed both, without added load as well as with the maximum normal use payload which should be positioned at the end-effector (unless another location is more usual during normal use).

— If relevant for the specific use conditions, a further round of tests should be performed with the robot system set for “shared control", e.g. support level for compensation for weight of the relevant body parts of a utilizer or setting the force amplification level. The tests should be performed with the maximum normal use payload that should be positioned at the end-effector (unless another location is more usual during normal use). If applicable, in both modes also tests of the robot system under the SFC(s) identified in the risk assessment that may influence the SLV and perform these test under these SFC(s) should be performed.

— In case of an emergency stop or a protective stop, a system may behave differently. When a robot may actively move the monitored point back to a predefined location, and if it might be possible that the monitored point moves through an area that is not allowed by the ROM area setting, this situation should be validated as well.

— In case during movements, if other parts of the robot may also move through an area that is potentially hazardous, these situations should be noted. The safety of these impacts should be

validated, e.g. via a suitable SLV protocol, considering the HRC skill “limit physical interaction energy”.

E.5.2.4 Environmental Conditions

The validation tests should be performed under conditions similar to the normal use conditions.

However, if the risk assessment indicates that environmental conditions could have an effect on the SLV, the test should be performed under these relevant environmental conditions, or simulated versions of these conditions as well.

E.5.3 Test Execution

The measurement equipment should be preliminarily activated:

— the measurement equipment should be calibrated during test setup (if calibration is required);

— data logging should be ready for recording on all recording devices;

— all the sensors should be attached properly, especially when a previous execution of the SLV protocol resulted in a collision or sudden stop of the RACA robot.

The following test procedure applies for each specified test case separately.

1) The monitored point is moved to a predefined starting position.

2) The monitored point of the robot system is kept stationary for at least 1 second.

3) The monitored point is moved towards a target point, which is either inside or outside the predefined ROM.

4) After any single motion, the monitored point on the robot system should be stationary for at least 1 second before continuing.

This procedure should be repeated with various start and target point combinations. During these tests, attempts to move the robot system in areas where it is not allowed to move should be made.

These tests should be repeated under the different environmental and system conditions and those identified during the risk assessment that may affect the SLV.

E.5.4 Data Analysis

Results from the data analysis will result in a pass or no-pass. A pass will be when the results of the validation tests show that at no instant the monitored point moved outside of the ROM volume. During the data analysis the ROM limitation settings should be known. A no-pass will occur when the monitored point moves outside the ROM volume, taking the accuracy of the measurement system into account.

Acquired position data should be low-pass filtered. The following procedure can be applied:

1) acquisition of the position of reference point, either measured or by computation from the position of several markers;

2) acquisition of the position of the monitored point, either measured or by computation from the position of several markers;

3) computation the relative position of the monitored point with respect to reference point;

4) Check if the relative position is within the ROM space. In case of complex ROM, a software enabling geometric modelling may be useful.

E.5.5 Report

The following data need to be present in the documentation:

— if applicable: description of the shared-control settings of the robot system (e.g. level of support or level of force amplification);

— descriptions of the various test sequences executed;

— start/end point + prescribed path;

— robot speed under which the tests were performed;

— load applied to the robot system;

— system conditions (e.g. normal use, SFC, or even functional stop/reset, emergency stop);

— logging/tracking information (e.g. referencing a file);

— pass or no pass result derived from analysed data [yes/no]).

The form in E.7 may be used for reporting all test relevant information.

E.6 Bibliography

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[E.3] ISO/FDIS 10218-2:2021, Robotics– Safety requirements– Part 2: Industrial robot systems, robot applications and robot cells

[E.4] EN IEC 80601-2-78:2020, Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

[E.5] EN IEC 60601-1, Medical electrical equipment – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

E.7 Report Form

E.7.1 General

Description of robot system under validation			
Test date		ID of tester:	
Test/Sequence ID (Seq#)		Hazard ID	
Photo			

E.7.2 System and related conditions

Type of robot	
Manufacturer	
Model + Serial Number	
System Configuration	
Control Software	
Condition [Normal/SFC]	
Description (SFC)	
Functional stop? [Y/N]	
Emergency stop? [Y/N]	
Maximum velocity [m/s]	
Applied load [kg]	
Shared-control settings of the robot system	
Support level	
…	
ROM description:	
Location of ROM description file / description of ROM limits:	

E.7.3 Conditions: environment

Base Inclination angle [°]	
Total system acceleration [m/s^2]	
Environmental conditions possibly influencing sensor acquisitions	

E.7.4 Conditions: miscellaneous

Any relevant condition	
…	

E.7.5 Target metrics

Stayed in ROM [Y/N]	
Any collision [Y/N]	

E.7.6 Measurement system

Measurement system used:			
Measurement system Calibration date:		Measurement accuracy:	
Reference point location (relative to robot system position)			
X			
Y			
Z			

E.7.7 Test Results

Test ID					
Sequence N./ID	Start point	End point	Stayed in ROM [Y/N]	Collisions [Y/N]	Pass [Y/N]
	Motion path datafile				
	Other information				
Sequence N./ID	Start point	End point	Stayed in ROM [Y/N]	Collisions [Y/N]	Pass [Y/N]

	Motion path datafile		
	Other information		
…			
Test Result [Pass/Fail]			

E.7.8 Final information about the test

Date of testing	
Name of tester	
Overall conclusion	
Signature	

Bibliography

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[3] Bessler J., Prange-Lasonder G.B., Schaake L., Saenz J.F., Bidard C., Fassi I. et al. Safety assessment of rehabilitation robots: a review identifying HRC skills and current knowledge gaps. Front. Robot. AI. 2021, 8 p. •••

[4] European Parliament. Directive 2006/42/EC on Machinery; European Parliament: Brussels, Belgium, 2006.

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[12] European Parliament. Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). European Parliament, Brussels, Belgium, 2014

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