Being safe around collaborative and versatile robots in shared spaces

Protocol

Test prevention of spatial overreaching for the subject – Human in (shared) control – testing with instrumented limb

ROB-LRM-4

The purpose of this protocol is to validate the safety skill “limit range of movement” for rehabilitation robots, where a limb of a subject has a connection point with the robot (either free or restrained) and the robot can move that point within a 3D volume. The range of motion is assessed using an instrumented limb which is attached to the robot.

Readiness Level	Description
7	Protocol in published over the toolkit, under evaluation, and open for community feedback.

COVR is a community effort and values any honest feedback to our services. Please feel free to express your opinion about this protocol. The feedback form is only one click away. Thanks for making COVR even better!

Disclaimer: This protocol reflects the current and collectively developed state of the art in the validation of a specific safety skill for a collaborative robot. However, you may have to adapt the described validation procedure to be feasible for your particular application, circumstances and applicable regulations. Neither the COVR project consortium as a whole nor any individual partner of the consortium takes, therefore, any responsibility for the correctness and completeness of the validation procedure described here.

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CONTENTS

1 Introduction

The purpose of this protocol is to validate the safety skill "limiting a range of movement" in 3D of a RACA robot*[1] by restricting spatial range of motion for both its end-effector as well as any other part of the RACA robot*, in order to avoid physical damage to the patient connected to this RACA* robot.

The primary hazardous situation considered here is an over stretching of the subject/user limbs, where the distance between a proximal and a distal joint is too large.

A secondary hazardous situation that can be observed during execution of this protocol, is that parts of a robotic arm type RACA robot* may collide with parts of the body of the subject. Whether these collisions are within acceptable limits, should be validated using a suitable protocol, e.g.ROB-LIE-1.

Figure 1: Example of ROM related robot in a rehabilitation application (left) and LRM-skill test setup (right)

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	limit range of movement
System	robotic arm (RACA robot*)
Domain	Healthcare
Conditions	3D movement Co-controlled human/robot driven (so for the human it is an active movement)
Measurement Device(s)	Instrumented Limb* setup

[1] All terms followed by an asterisk * are defined in section §1.2

	Warning
	This protocol supports users only to validate the effectiveness of the skill listed in the profile above. The skill should be a technical measure for the robot system to mitigate the risk of one potentially hazardous situation as identified in the mandatory risk assessment. Consequently, the risk assessment must be done before using this protocol.

1.2 Definitions and Terms

Active movement (source: local to the document)

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.

Direct path (source: local to the document)

A movement trajectory between two points, where the path is depending on robot path planning (can be linear in space or not if interpolation is done on joint coordinate)

Emergency stop (source IEC 80601-2-78)

Manually initiated interruption of operation intended to stop the RACA robot* to prevent harm

End-effector (source: ISO 8373)

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 (IEC 80601-2-78).

Human Tester (source: local to the document)

Qualified person who executes the test

Instrumented Limb (source: local to the document)

Mechanical device, resembling a human limb, equipped with angle sensors and with known segment lengths, so joint angles and spatial distances between proximal and distal point on the device can be determined

LRM (source: local to the document)

Limit Range of Movement

Monitored point (source: local to the document)

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 monitored point is to be represented by the subjects' hand, it might be defined as a point in a fixed distance from the arm splint.

Overreaching (source: local to the document)

A movement that results in the Monitored point exceeding the range of motion. Can be harmful to the subject as the movement can exert an excessive strain on joints.

Passive movement (source: local to the document)

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. So, the passive aspect is viewed from the human perspective.

Predefined path (source: local to the document)

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

Protective stop (source: IEC 80601-2-78)

interruption of operation automatically initiated by the RACA robot*, that allows a cessation of motion for basic safety and essential performance purposes, which could allow the programmable electrical medical system (PEMS)/programmable electronic subsystem (PESS) to facilitate a restart

RACA robot (source: IEC 80601-2-78:2019 – clause 201.3.212)

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

Range of Motion (ROM) (source: local to the document)

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 a human subject 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.

Reference point (source: local to the document)

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 shall represent the expected location of the subjects' shoulder joint center, 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.

Rehabilitation robot (source: local to the document)

RACA robot used in rehabilitation

S.F.C. / **Single fault condition** (source: IEC 60601-1 definition 3.116)

A condition of Medical Electrical equipment in which a single means for reducing a risk is defective or a single abnormal condition is present

Target point (source: local to the document)

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

2 Concept and Objectives

2.1 Hazardous Situations

During rehabilitation, the RACA robot* will be attached to a patient, in order to mobilize a limb or to assist the use of the impaired limb in daily life. Based on the initiated movement by the patient, 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 subject as well as the required movement types, the therapist will set some specific boundaries to the movements of the robot arm, in order to make sure the distance between a proximal joint center (e.g. shoulder or hip) and a distal joint center (e.g. wrist or ankle) stays within a certain area.

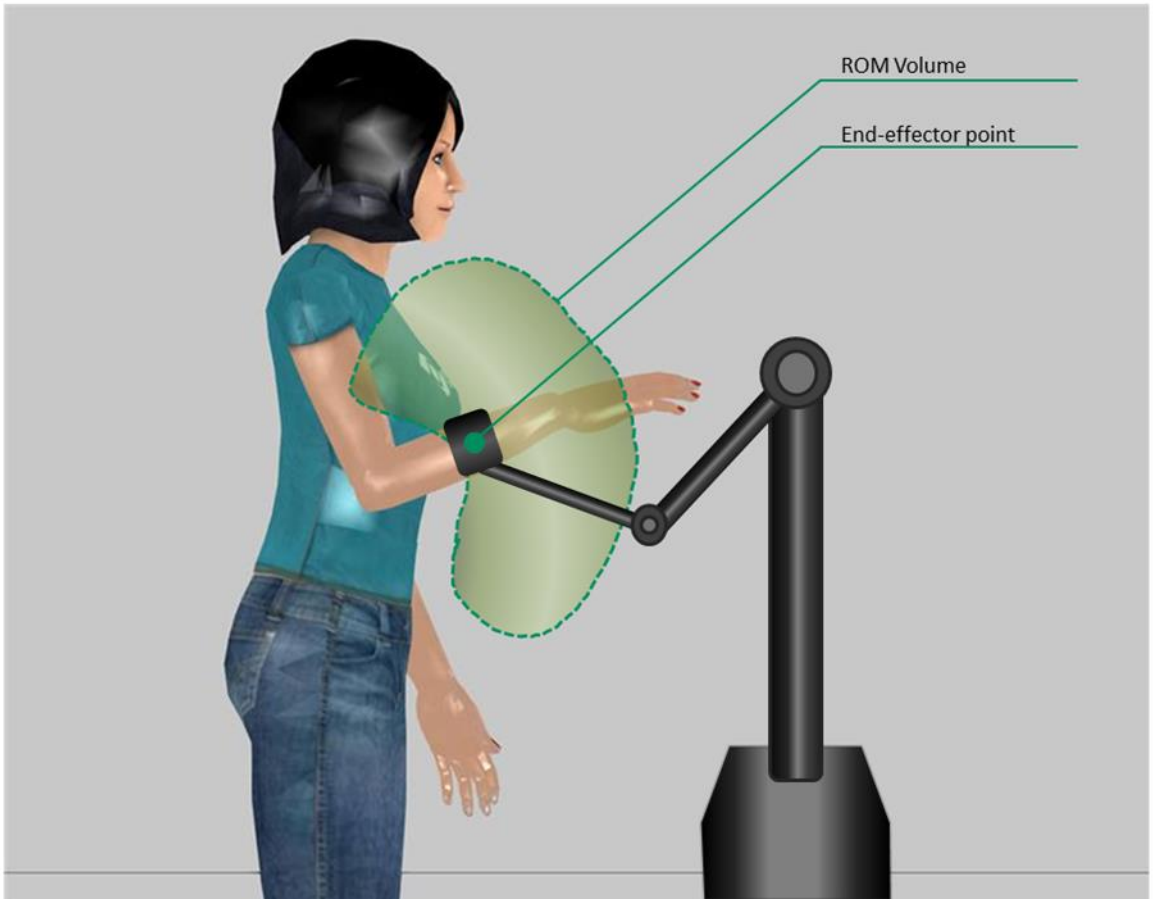

Figure 2: example of use situation - subject may also be seated

The hazardous situations considered in this protocol are:

- over stretching of the subject/user joints/limbs, where the distance between a proximal and a distal joint is too large.
- the robot arm moving through a space where a subject's body parts are located.

2.2 Target Behavior and Metrics of the Safety Skill

The target behavior of the skill to be validated is to validate whether the rehabilitation robot keeps the relative displacement between a reference point* and the monitored point* within the specified ROM*.

The movements of a RACA robot * with shared control are mainly defined by the input of the human and the co-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 Direct path* between 2 points or, more likely, a more variable trajectory between 2 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 defining 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 ROM description of the 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 skill is effective enough to achieve the specified level of risk reduction. They represent a threshold that the output values of the test must not exceed for considering the test as passed. These values for the ROM* in a 3D space can be variable during intended use and may be determined by a therapist for the individual user. Therefore, the systems' ability to keep the end-point within the set safe area needs to be validated using different settings for the ROM*, including 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 RACA robot* move through spatial areas where other body parts of the patient are. Please note during this test whether parts of the RACA robot* are kept clear from other body parts of the subject.

For this validation protocol, the target metrics are:

- Does the monitored point* move outside the defined ROM*? (TRUE/FALSE)
- Does any part of the robot enter an area where it may collide with any part of the body? (TRUE/FALSE)

Please report the values of the target metrics for each test using the form in Annex A (§7.1).

3 Conditions

In case the conditions under which the hazardous situation may occur can change, the user of this protocol shall develop a test plan containing all their reasonable and relevant combinations. The user must test the applied skill for each combination of this list. Therefore, it is important to know the conditions with the most significant influence on the target metrics. Please report all conditions, represented by values, for each test using the form from Annex A (§7.1).

3.1 System

The term system refers to the rehabilitation robot consisting of:

- a robot arm, that is intended to move a body part within a specified workspace (ROM*)

- a base the robot is mounted on, which is also connected to the support base for the subject
- optionally a cuff or splint attached to the monitored point of the robot arm to fixate a single body part

Apply this protocol for the complete system as it is normally used. Perform the tests both under normal use conditions as well as relevant S.F.C.* which may influence the safety skill, like:

- When an emergency stop* or a protective stop* is initiated.
- The S.F.C.* where invalid sensor data may influence the controller behavior or the applied risk reduction measure (RRM)
- The S.F.C.* where failure of an actuator may influence the behavior of the controller or the RRM

During the risk assessment special attention should be paid to properly identify relevant S.F.C.*s.

- This protocol can also be applied with an applied part connected to the endpoint of the robot, e.g. a splint, which, in normal use, is connected to a body part of the subject with the intention to move that body part, as long as the movements of this subsystem are predictable in relation to the motions of the robot arm.
- This protocol does not consider a robot arm where the relation between the robot arm and the subject is not fixed.

3.2 Environment

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

- Inclination angle of the total robot (e.g. when the robot arm is mounted on a mobile robot)
- Externally induced motions/accelerations of the total combination of RACA robot* and the human (e.g. when both the RACA robot* 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.

4 Setup

4.1 Sensing devices

For validation of this safety skill, an Instrumented Limb* setup is used. This Instrumented Limb* is equipped with angle sensors in the joints that can detect the angles of the limb segments relative to each other. The size of the Instrumented Limb* segments can be adjusted, so the tests can be performed for a variety of human sizes. These lengths should be selected in a way that they can reach the ROM* to be investigated. Combining the segment lengths and the joint angles from the Instrumented Limb* can be used to calculate the actual ROM* during movements.

In case the maximum reach point of the subject attached to the RACA robot* does not correspond with the end effector point* of the RACA robot*, but the ROM* in the RACA robot* is described as that point on the subject, the reach point of the subject should be considered as the end effector point* and thus be defined as part of the Instrumented Limb* (as the monitored point*).

In Figure 3 the concept of such an instrumented limb* is shown, where the stand is the supporting structure that keeps the instrumented limb* in a defined location. At the top of the stand is an angular

encoder that registers the rotation of the arms segments in a horizontal plane relative to the global reference frame. Above that is an angular encoder that will register rotations in the vertical frame. Two other encoders are mounted on segment A, that register the rotation around the longitudinal axis of segment A and the rotation between segment A and segment B. Segments A and B and the height of the stand can be modified to mimic different limb dimension.

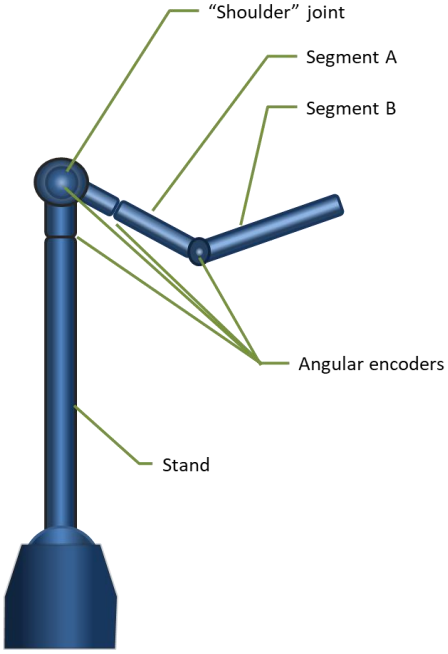

Figure 3: Conceptual image of the instrumented limb

⚠	**Warning**
	Make sure the length of the segments of the Instrumented Limb* are set in such a way that these freely allow movement outside of the predefined ROM*

4.2 Method

The Instrumented Limb* will be positioned relative to the RACA robot* in such a way that it resembles the human limb positioning during a normal use situation and its base has a well-defined position to the reference point*, which is used to define the ROM* for the RACA robot* (see Figure 3). For convenience the reference point* can be chosen as representing the proximal joint of the limb for which the device is validated, i.e. the shoulder joint for the upper limb and the hip joint for the lower limb.

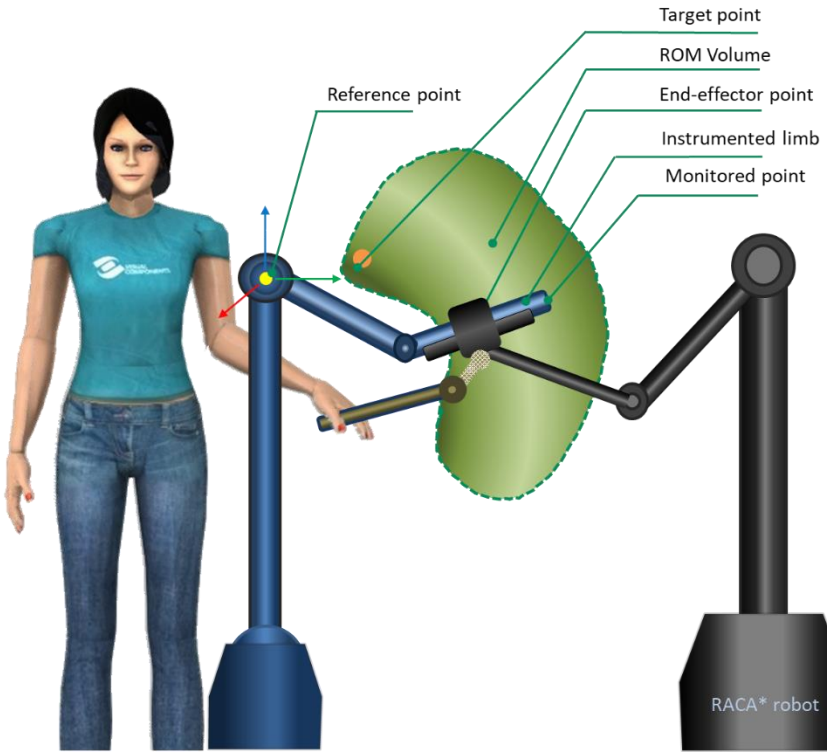

Figure 4: General structure of the test arrangement with an Instrumented Limb and a Human Tester**

Since the robot arm uses shared control, when safely possible, the movements can be applied by a Human Tester*.

However, a proper risk 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*. Main criteria will be:

- The Human Tester* should be able to remain out of reach of the robot arm during the test.
- If that is not possible, the Human Tester* should be in a position where during the tests contact with parts of the Instrumented Limb* is highly unlikely, but the Human Tester* can still move freely away from potential collision by either the robot arm or the Instrumented Limb*.
- During the execution of the test, the tester should hold a 3-position enabling switch, which acts as an emergency stop so the robot can be stopped immediately when a dangerous situation may arise.

4.2.1 Data acquisition

Data acquisition of the sensors of the Instrumented Limb* should be continuous during the test, so the entire motion trajectory can be reconstructed after the test. The acquisition rate used for reading the sensors of the Instrumented Limb* should be at least a factor 10 higher than the highest expected frequency component of the movements of the robot during the test.

After data acquisition the data has to be processed to determine whether during the test the monitored point* gets located outside the predefined ROM* volume. The measured location data may be filtered to remove high frequency measurement inaccuracies, but this filter may not use a cut-off frequency lower than 5 times the highest expected frequency component 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, will usually suffice.

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

5 Procedure

5.1 Test Plan

The test plan is a summary of 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 to validate the skill for the considered application.

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 RACA robot*, 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 RACA robot* exceeds this volume or not.

According to Chapter 3, the protocol must consider the following conditions:

- For defining the motion trajectories, consider that 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 part of the direct path* could cross an area outside of the specified ROM* volume, should this be the shortest route
    - Trajectories where parts of the RACA robots* may collide with parts of the subject's body.
- Tests must be run as much as possible at maximum speed with specified maximum allowed load for the RACA robot* and under otherwise normal use conditions. This load should be positioned in such a way that its center of mass would be close to the end-effector of the RACA robot*, unless another location is more conform normal use conditions.
- If ROM* settings can be modified by the user, 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 safety skill.
- Repeat the tests mentioned above also under single fault conditions that may have an effect on the safety skill.

5.2 Preparation

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.

- Prepare a number of test sequences and specify these in the report

5.2.1 Test Arrangement

For preparing the validation setup:

- Calibrate the sensors of the Instrumented Limb* (if necessary).
- Place the Instrumented Limb* in a defined position near the RACA robot* in such a way that it is able to freely reach the spatial locations and motion paths required during the tests.

- Attach the Instrumented Limb* to the RACA robot*.

5.2.2 System Conditions

Please report the system composition for each single test using the form in Annex A.

- If possible tests should be performed with the device in “passive”/”hand guiding” mode, where the RACA robot* only supports its own inertia.
    - Perform this test 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)
- Next tests should be performed under normal use condition, with the RACA robot* with typical normal use “shared control" settings, e.g. support level for compensation for weight of body part of user
    - The tests should be performed with a payload, which should be the maximum normal use load which should be positioned at the end-effector* (unless another location is more usual during normal use)
    - Velocity during tests should be the maximum velocity that the robot can achieve
- In both modes also test the RACA robot* under the S.F.C.*(‘s) identified in the risk analysis that may influence the safety skill and perform these tests under these S.F.C.*(’s).
- In case of an emergency 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 protocol (e.g. ROB-LIE-1).

5.2.3 Environmental Conditions

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

However, if environmental conditions may have an effect on the safety skill, the test should be performed under these different environmental conditions, or simulated versions of these conditions as well.

5.3 Test Execution

Activate the measurement equipment

- Make sure the Instrumented Limb* is calibrated (if calibration is required)
- Make sure data acquisition is ready for recording the data from the sensors in the Instrumented Limb*.
- Make sure the Instrumented Limb* is attached properly to the RACA robot*, especially when a previous execution of the protocol resulted in a collision, a sudden stop of the RACA robot* or the Instrumented Limb* getting detached from the RACA robot*.

Apply the following test procedure for each specified test case separately.

- Move the monitored point* to a predefined starting position.
- Make sure the monitored point* of the RACA robot* is stationary for at least 1 second.

- Move the monitored point* either via a direct or an indirect path through the target volume to a target point.
- After a successful motion, make sure that the monitored point* on the RACA robot* is stationary for at least 1 second before continuing.

Repeat this with various start point and target point combinations. Make sure that during at least half of these tests, attempts are made to move the RACA* robot into areas outside of the allowed ROM*.

Repeat these tests under the conditions mentioned in §5.2.3 and §5.2.2 and those identified during the risk analysis that may affect the safety skill.

5.4 Data Analysis

To determine whether the system passed this test:

- In the data analysis the segment lengths of the instrumented limb* should be combined with the joint angles between the segments of the instrumented limb* for each point in time during the test. This will provide the required information about the imposed spatial ROM*.
- Results from this 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.
- Very short and limited “overshoots” in movement may be allowable. However, these acceptability criteria should be specified and properly documented by the manufacturer. These criteria should consist of a maximum overshoot magnitude, combined with a maximum duration of the overshoot as well as a supporting rationale. As a guideline an overshoot with a magnitude of 10mm and a duration of 1 second could be acceptable.

5.5 Report

The following data needs to be present in the documentation:

- Description of the support settings of the RACA robot*
- Descriptions of the various test sequences executed
- Start/end point + direct path / prescribed path
- Robot speed under which the tests were performed
- Load applied to the robot
- System conditions (e.g. normal use, single fault, functional stop/reset, emergency stop)
- Pass or no pass result derived from analyzed data (yes/no)
    - When the target point* is within ROM*:
      Provide logging/tracking information about the motion path used, to determine the RACA robot* hasn’t moved outside of the allowed ROM*.

6 Bibliography

EN IEC 60601-1:2006

EN IEC 80601-2-78:2020

7 Annexes

7.1 Report Form

Avoid single axis rotation beyond pre-set limits for individual PATIENT movement

Test form - Protocol ROB-LRM-4			
Test date		**Name of tester:**	
Sequence ID (Seq#)		**Hazard ID**	
Description of RACA robot* under validation			
Measurement system used:			
Measurement system Calibration date:		**Measurement accuracy:**	
Condition	Normal/S.F.C.*	**Description (S.F.C.*):**	
		Functional stop?	
		Emergency stop?	
		Max velocity (m/s)	
		Applied load (kg)	
		Inclination angle (˚)	
		Total system acc (m/s²)	
Instrumented Limb*:			
"Shoulder" height:			
proximal segment length:			
Distal segment length:			
Instrumented Limb* position (relative to RACA robot* position)			
X			
Y			
Z			
Support level settings of the RACA robot*			
Support level:			
ROM description:			
Location of ROM description file / description of ROM limits:			

Test ID (Seq#-id)	Start point	Endpoint		Stayed in ROM* (Y/N)	Collisions (Y/N)	Pass? (T/F)
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					
Seq#-ID	**Start**	**End**		**In ROM***	**collisions**	**Pass?**
	Motion path datafile:					

Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					
Seq#-ID	Start	End		In ROM*	collisions	Pass?
	Motion path datafile:					

Final Information about test

Date of testing	
Name of tester	
Overall conclusion	
Signature	