Being safe around collaborative and versatile robots in shared spaces

Protocol

Test limitation of vertical Range of Motion (falls prevention)

(WSU-LRM-1)

This protocol can be used to validate the ability of a Weight Support System, used in the healthcare domain, to prevent falls by limiting the Range of Vertical Motion.

Readiness Level	Description
7	Protocol is 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.

Grant agreement no. 779966
Date November 15, 2021

COVER
safearoundrobots.com

CONTENTS

1 Introduction

The purpose of this protocol is to validate the Limit Range of Motion safety skill that is often used in a (partial) body weight support RACA robot*. In normal situations a subject will receive (partial) body weight support either to allow the subject to perform exercises in a safe environment. The weight support usually is equal at different heights, since during exercises, the Center of Mass (COM) of the subject usually varies in height. Limiting the range of motion means here protecting the user from falls and is often implemented based on a minimum allowable height for the subject or on too high downward velocity

Figure 1: Left: Subject in a (partial) Weight Support system, Right: Concept of the test setup

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	Limit Range of Motion
System	Weight Support systems / Balance trainer
Domain	Healthcare
Conditions	Indoor
Measurement Device(s)	Crane (for mimicking behavior/controlling the vertical position of the simulated subject), Wire encoder (for height measurement) 1D (tensile) force sensor (cable mount)

⚠	**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 <u>one</u> 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

Applied Part (source: IEC 60601-1 definition 3.8)

Part of medical electrical equipment that in normal use necessarily comes into physical contact with the patient for the medical electrical equipment or a medical electrical system to perform its function

Actuated Applied Part (source: IEC 80601-1-78 definition 201.3.201)

Subcategory of APPLIED PART that is intended to provide actively controlled physical interaction with the patient that are related to the patient's movement functions, to perform a clinical function of a RACA robot.

Harness (source: local to the document)

Usually, an actuated applied part of the RACA robot*, which functions as a body holding device that distributes the forces for maintaining the body posture, or that occur during a fall, over a large area of the body.

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)

The movement range that describes the dynamic vertical displacement in which the weight support should work correctly.

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

Weight support system (source: local to the document)

A robotic system that is used to actively support (part of) the body weight of a patient.

2 Concept and Objectives

The concept of the validation process is to simulate the RACA robot* supporting a specified weight. An additional platform, that can be dynamically adjusted in height, is used to mimic normal use situations where the height of the mass variates during exercises. During the test, the RACA robot* must operate under the same conditions as it will in its real application. Objective of the test is to validate by measurement whether the implemented safety skill “Limit Range of Motion” functions correctly.

2.1 Hazardous Situations

In weight support type RACA robots* often an active applied part* is used to provide (partial) weight support to a patient. The amount of support usually can be set by a therapist, so an appropriate support is applied to the patient during rehabilitation exercises. Such a device is usually implemented to support the subject during training of daily activities, while the patient may not be fully able to support their body weight. Because the patients can be challenged during these exercises, there is a risk for falls.

In normal use these (partial) weight support systems usually allow a certain amount of vertical movement, so the subject can perform the intended motion. When the patient loses balance and falls, the weight support RACA robot* should detect that an prevent the patient from falling.

A hazardous situation will occur when the fall is not detected and the patient is not protected by the system, thus when the weight support system fails in limiting its range of motion (and, consequently, patient motion).

2.2 Target Behavior and Metrics of the Safety Skill

The target behavior of the skill to be validated is to determine whether, with the settings for a specific therapy task, the falls detection works as intended.

The target metrics is bases on physical and measurable values. A fall should be stopped in a controlled manner before the subject hits the ground.

For validating the robot skill, the output values are:

- Does the RACA robot* catch the weight and hold in in place?
    - Metrics: [Y/N]
- or does the RACA robot* catch the weight and then lowers it to the floor, not exceeding a max vertical velocity during the lowering down.
    - Metrics: [Y/N] and the maximum velocity is lower than a maximum lowering velocity

Please report the values of the target metric, including possible safe/acceptable margins for each test using the form in the Annex.

Additionally a visual inspection of the harness and harness attachments should be executed, according to the inspection guidelines in Annex B and reported, to make sure these components meet the safety criteria.

3 Conditions

3.1 System

The term system refers to a robotic weight support system, usually consisting of a support structure, an attachment structure, where a harness for the subject can be attached and which usually will dynamically adjust the height, according to the need for the exercises.

The protocol user must consider different support levels in combination with different working heights as well as possible settings for allowable dynamic height variations as different system related conditions.

The protocol user must consider the implemented safety measures of the RACA robot*, in order to select the relevant tests for the RACA robot* under test, i.e. a minimal position test or a maximum velocity test should only be performed when relevant. A free fall simulation should be tested in any case.

3.2 Environment

No specific environmental conditions are expected to be relevant for this skill

3.3 Miscellaneous

As with all medical devices single fault conditions* that may be relevant for a proper functioning of the safety skill should also be considered.

4 Test Setup

4.1 Equipment

During the test the following equipment is used during the test.

- Weights (by default 150kg), including a frame for lifting the weights by the weight support system
- A crane is used to control the weights. This crane should be stable and should have sufficient power to control the weight position and speed.
- A wire encoder is used to determine the vertical position of the weights during the test
- A 1D force sensor is used to determine the amount of weight supported by the RACA Robot*
- A data acquisition system that captures the data from the force sensor and the wire encoder at a minimum sampling rate of 100 Hz

4.2 Method

Weights are placed in a cage or bag that will be attached to harness attachments of the weight bearing system during the test, thus simulating a subject in the harness. The weight is also connected to a crane by an additional attachment. For protection of the floor, the floor under the weights is covered by a rubber layer with a thickness of at least 2cm.

During the tests the height of the weights will be varied over a pre-described ROM* using the crane. This ROM* should not exceed ranges specified by the manufacturer, nor should the downward speed of movement exceed the maximum normal use movement velocity.

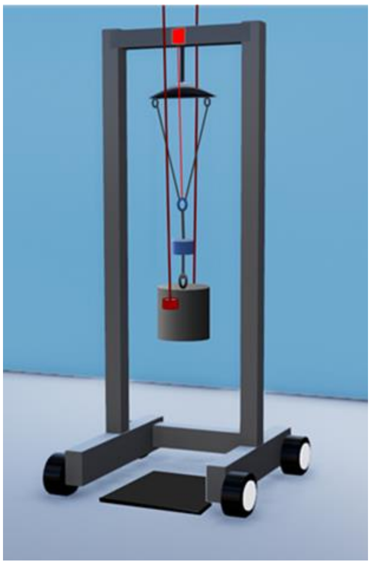

Figure 2: Structure of the test arrangement (crane attachment depicted in dark red, wire encoder in light red)

At a random moment crane will either

- release the weight support completely, simulating a free fall
- move the weights to a position lower than the allowed minimum height, according to the settings in the robot, if this is implemented as a safety measure in the control of the RACA robot*
- move the weight down fast, faster than the allowable vertical motion velocity, if this is implemented as a safety measure in the control of the RACA robot*.

A wire encoder is used to determine the height of the weight and monitor its movements. When the weight gets lower than the predefined minimum height, the downward motion should be stopped or decelerated by the RACA robot*. And a force sensor is used to monitor the amount of weight support by the RACA robot* during the test.

As described in §2.2 the test will be successful when either:

- the RACA robot* prevents the weight hitting the floor
- or when the weight is lowered to the floor in a controlled way at a velocity lower than a safe maximum velocity..
  This maximum velocity can possibly be obtained from the risk analysis of the manufacturer. If it is not defined there, a controlled lowering velocity (Vel_{max}) of max 0.2m/s can be assumed safe.

The full test sequence should be repeated at least 3 times for each of the relevant test options (to check for possible inconsistencies between sessions), unless the test fails.

Additionally a visual inspection of the harness used during normal used and the attachments should be performed in a systematic manner. The procedure for this is described in annex B of this protocol.

5 Procedure

5.1 Test Plan

For the test plan, a number of weight support levels in different ranges should be selected, so the result of the validation tests may be assumed valid for the various support levels during normal use.

The weight ranges can be:

- One support level in the 10-40% weight support range
- One support level in the 41-70% weight support range
- One support level in the 71-100% weight support range

If possible, relevant single fault conditions* should be considered as well and tests should be performed under these conditions.

Each combination of these conditions represents a particular test case.

5.2 Preparation

Before executing a particular test from the test plan, it is necessary to prepare the setup and the conditions properly. A crane with sufficient power and good stability should be used.

The following sections gives instruction to prepare each part of the setup and all conditions with a significant influence on the target metrics.

5.2.1 Test Arrangement

Prepare the validation setup:

- Place the rubber floor cover on the floor at the location where the tests will be executed
- Place a frame to hold weights under the weight support system
- Add the weights in this frame. Unless otherwise specified by the manufacturer, a minimum total mass of 150 kg[1] should be used.
- Position the crane over the weight support system
- Connect the frame with the weights to the crane by means of a system enabling commanded release.
- Lift the weight by the crane to the required height at which the weight can be attached to the harness attachment point.
- Attach the 1D force sensor to the attachment points for the harness on the RACA robot*
    - Connect the 1D force sensor to the data acquisition system
    - Make sure the 1D force sensor is calibrated and sufficiently warmed up
    - Zero level the 1D force sensor or record an offset level measurement for the output for the unloaded sensor.
- Attach the frame to the harness attachment points via the 1D force sensor, using a method that has sufficient strength to withstand the tests.
- Attach the wire encoder to the weight support system above the attachment point for the weights
    - Connect the wire encoder to the data acquisition system
    - Attach the wire of the encoder to the frame with the weights (or a point from which the height of the weights can be directly derived).

[1] According to IEC 60601-1: a minimum mass of 135kg for the patient and 15 kg for accessories

  - Determine the offset between the wire encoder output and the height of the CoM of the weights
- Lower the crane to the required height for the tests.

5.2.2 System Conditions

- Make sure the system is started and prepared for normal use as described in the user manual
- Set the weight support level at one of the pre-selected levels as defined in the test plan, i.e.:
  - one support level in the 10-40% weight support range
  - one support level in the 41-70% weight support range
  - one support level in the 71-100% weight support range

Please report the system condition for each single test in the form in the Annex

5.2.3 Environmental Conditions

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

However, if the risk analysis indicates that environmental conditions could have an effect on the safety skill, the test should be performed under these relevant environmental conditions as well. The specific environmental condition must be reported in the form in Annex A.

5.3 Test Execution

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

- [step 1] Check that the weight is securely attached to the crane
- [step 2] Check that the weight is securely attached to the harness attachment point of the RACA robot*
- [step 3] Set the required support level in the system
- [step 4] Start the data acquisition system
- [step 5] Keep the setup stationary for 5 seconds to capture the values for full weight support by the movable platform
- [step 6] Set the required support level on the RACA robot*
- [step 7] Set the allowable ROM* for the vertical motion (when possible)
- [step 8] Start the weight support function of the RACA robot*
- [step 9] Keep the crane stationary for 10 seconds
- [step 10] Start the selected test motion of the crane
- [step 11] Observe what happens during and after the simulated fall
  - During: Unobstructed fall / falling weight is caught
  - After: held in place / controlled lowering to the floor (either manual or automatic)
- [step 12] Keep the crane stationary for 10 seconds
- [step 13] Lower the set weight support level on the RACA robot* gradually to zero as described by the manufacturer, to make sure that the weight support is properly released in a controlled way
- [step 14] Move the crane up to make sure the weight is only supported by the crane
- [step 15] Keep the setup stationary for 5 seconds
- [step 16] Stop the data acquisition system
- [step 17] Repeat this test 3 times

After all tests are done:

- Make sure the weight is only supported by the crane
- Make sure the RACA robot* is set setting where it is not supporting the weight
- Move the weight up using the crane, until the weight can be safely removed from the harness attachment points.
- Detach the wire encoder from the weight
- Detach the weights from the RACA robot*
- Use the crane to safely lower the weight to the floor
- Disconnect the wire encoder and the force sensor from the data acquisition system
- Detach the wire encoder and the force sensor from the RACA robot*

5.3.1 Visual inspection of the Harness

Execute the visual inspection protocol for the harness as described in Annex B of this protocol and report this using the form from Annex B2

5.4 Data Analysis

Data from the 1D force sensor and the wire encoder can be filtered using a 10Hz Low pass filter.

The velocity of movement can be derived from the wire encoder data by calculating the height difference of the heights over a 3- or 5-point interval:

3-point interval : $$v_n = \frac{|h_{n+1} - h_{n-1}|}{t_{n+1} - t_{n-1}}$$

5-point interval : $$v_n = \frac{|h_{n+2} - h_{n-2}|}{t_{n+2} - t_{n-2}}$$

Where v_n is the velocity at sample index n

h_n is the height (in meters) at sample index n

t_n is the time (in seconds) at sample index n

The test will be a PASS when:

- When after the "fall" the downward motion is stopped and kept stationary, this counts as a PASS.
- When after the "fall" the downward motion continues (or is resumed), but during that downward motion the weight remains fully supported by the RACA robot* (if the measured weight is significantly less than the actual weight, the test has not been correctly executed and part of the weight will probably have been supported by other parts of the test setup) and the downward motion does not exceed Vel_{max}.(i.e. 0.25m/s or another allowable value, based on the risk analysis), this counts as a PASS

Otherwise the test is considered a FAIL.

Should the inspection of the harness lead to a FAIL on the harness safety, this will mean a FAIL of the entire test. However, the main part of the test still stands and doesn't need re-execution when the harness is timely repaired or replaced by a harness that passes the inspection, provided that, apart from the harness, no significant changes were made to the RACA robot*.

5.5 Report

For documenting the test results, the form in the Annex A can be used.

This report should contain:

- The make, type and serial number of the RACA robot*
- The type if test (Free fall / Minimum Height / Max velocity)
- The maximally acceptable velocity that may be used to lower a subject safely to the floor
- The support level setting for the RACA robot* during the test
- The amount of weight used during the test
- Information about the sensors and crane used during the test

And for the outcomes of the test

- Was during the test the weight stopped and held in place
- Or was the vertical motion stopped and after the stop the weight was lowered to the floor
    - If so, wat was the maximum velocity during that lowering
    - The weight, supported by the RACA robot*, during the lowering down phase

6 Bibliography

EN IEC 60601-1: 2006

EN IEC 80601-2-78:2020

OSHA Lifeline Harness Inspection Guide

Annex A: Test form

Test form protocol WSU-LRE-1			
Test date		**Name of tester**	
Sequence ID			
System conditions			
RACA robot* under test (name and type)			
RACA robot* SN			
Support level used			
Max lowering velocity (Vel_{max})			m/s
Total weight used			kg
Environmental conditions			
Miscellaneaous conditions			
Fall simulation method	Free fall / Minimum Height / Max velocity		… m or … m/sec
Measurement devices			
1D force sensor used		**Type**	
Calibration date		**SN**	
Crane model + type			
Crane SN			

Test sequence				
Test nr			**Remarks**	**PASS/FAIL**
1	**Fall stopped and kept stationary**	Y / N		
	Fall stopped and lowered to floor	Y / N		
	Force during lowering [N]			< Weight ?
	Max velocity during lowering [m/s]			$<Vel_{max}$?
	Conclusion			PASS / FAIL

2	**Fall stopped and kept stationary**	Y / N		
	Fall stopped and lowered to floor	Y / N		
	Force during lowering [N]			< Weight ?

	Max velocity during lowering [m/s]			<Vel_{max}?
	Conclusion			PASS / FAIL

3	**Fall stopped and kept stationary**	Y / N		
	Fall stopped and lowered to floor	Y / N		
	Force during lowering [N]			< Weight ?
	Max velocity during lowering [m/s]			<Vel_{max}?
	Conclusion			PASS / FAIL

…	**Fall stopped and kept stationary**	Y / N		
	Fall stopped and lowered to floor	Y / N		
	Force during lowering [N]			< Weight ?
	Max velocity during lowering [m/s]			<Vel_{max}?
	Conclusion			PASS / FAIL

Final Information about test

RESULT	**PASS/FAIL**		
Result of test			
Result of harness inspection (Annex B)			
Overall conclusion			
Date of testing		**Name of tester**	
Signature			

Annex B1: Visual Inspection procedure for Harness safety

Based on the OSHA Lifeline Harness Inspection Guide

- [step 1] Check labeling of the harness.
  - Register the serial number and date of manufacturing in the report.
- [step 2] Retrieve or compile an overview image of all the separate components of the harness and include it in the report (Annex B2)
- [step 3] Check the material of the harness for any damage and signs of wear
  - Check for damage like warn webbing, (localized) stretching, cuts,
  - Check for loose stitching
  - Check for discoloration
  - Check for possible evidence of potential uncertified repairs
- [step 4] Check the material of the straps of the harness for any damage and signs of wear
  - Check for damage like warn webbing, (localized) stretching, cuts,
  - Check for loose stitching
  - Check for discoloration
  - Check for possible evidence of potential uncertified repairs
- [step 5] Straps, rope and lanyards
  - Check for loose stitching, stretching, broken fibers
  - Check for discoloration
  - Check for possible evidence of potential uncertified repairs
  - Check clips on straps for damage or loose stitching
- [step 6] Check buckles, loops, D-rings, clamps, clips etc.
  - Check for rust, small cracks
  - Check that parts aren't bent or broken or chipped
  - Check for possible sharp edges
  - Check for possible evidence of potential uncertified repairs
- [step 7] Attachment point on the robotic device
  - Check for any damage the attachment points on the robotic device
  - Check for any damage on the attachment point on the harness/lanyard etc.
  - Check for a proper fit of the harness attachment points and the attachment points on the robotic device

Annex B2: Visual Inspection registration form

WSU-LRM-1 – Harness visual inspection			
Test date:		**Tested by**	
Harness description		**Model nr**	
Harness SN		**Date of manufacture**	
SCHEMATIC OF HARNESS TO INSPECT			
INSERT OVERVIEW IMAGE OF HARNESS AND NUMBERED COMPONENTS			

VISUAL INSPECTION

Material of the Harness		• Damage, cuts, tears, localized stretching • Loose stitching Discoloration • Uncertified repairs	
Item nr	**Observation**	**Results**	**Comments**
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
Material of the straps of the Harness		• Damage, cuts, tears, localized stretching • Loose stitching Discoloration • Uncertified repairs	
Item nr	**Observation**	**Results**	**Comments**
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
Straps, rope lanyards		• Loose stitching, stretching, broken fibres • Discoloration • Uncertified repairs	
Item nr	**Observation**	**Results**	**Comments**
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
Buckles, loops, D-rings, clamps, clips etc.		• Rust, Small cracks • Parts bent or broken or any other damage • Any sharp edges • Uncertified repairs	
Item nr	**Observation**	**Results**	**Comments**
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	

		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
Attachment points:	• On robotic device • On harness • Proper fit between robotic device and harness		
Item nr	**Observation**	**Results**	**Comments**
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	
		PASS / FAIL	

Final result	**PASS / FAIL**
REMOVE FROM SERVICE	**RETURN TO SERVICE**
Name or tester	
Signature:	