Being safe around collaborative and versatile robots in shared spaces

Protocol

Test correct weight support Level – using crane

(WSU-LRE-2)

This protocol can be used to validate the weight support level for Weight Support Systems used in the healthcare domain, where the amount of weight support can be varied by a therapist according to the need for the therapy of a subject.

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!

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National Research Council of Italy
Roessingh Research and Development

Grant agreement no. 779966
Date October 27, 2021

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1 Introduction

The purpose of this protocol is to validate the support level entered for a (partial) body weight support system. In normal situations a subject will receive (partial) body weight support either to prevent falls or 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. The skill to be tested is to limit the restraining energy.

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 Restraining Energy
System	Weight Support systems
Domain	Healthcare
Conditions	Indoor
Measurement Device(s)	1D Force sensor, crane

⚠	**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 an 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.

COM (source: local to the document)

Center of Mass

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 lifting a specified weight with the robotic system and weights that represent the weight to be lifted, combined with a crane that can be dynamically adjusted in height to mimic height variation of the mass 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 applied safety skill "limit interaction energy" operates correctly.

2.1 Hazardous Situations

In weight support type RACA robots* 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.

In case the support level is either substantially incorrect or inconsistent relative to the support level set by a therapist, this may lead to a hazardous situation. The subject may be lifted too much, which may cause discomfort and possibly induce skin abrasions. The subject may also be insufficiently supported by the RACA robot* or the timing of the support could be incorrect. This could also cause discomfort and possibly lead to stumbles or even falls.

2.2 Target Behavior and Metrics of the Safety Skill

The target behavior of the skill to be validated is whether the amount of (partial) weight support provided by the RACA robot* corresponds with the amount of support entered by the therapist in the RACA robot* settings.

The target metrics are based on physical and measurable values, which are defined by the therapist and are entered in the RACA robot* by the user. These values represent safe values for using the RACA robot* in a safe and effective way.

For validating the robot skill, the output values are:

- The amount of actual weight support for the selected weight support levels, expressed in a force or weight measure.
- The amount of weight support during variations in height at different support levels, expressed in a force or weight measure.

The risk assessment should include safe/acceptable deviations for the output metrics. An inaccuracy of 5% can be accepted for safe use. A variation in weight support of about 5% during height variations can be considered acceptable for safe use (unless otherwise stated in the instructions by the manufacturer).

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

3 Conditions

3.1 System

The term RACA robot* or system in this document refers to a robotic weight support type RACA robot*. This system usually consists of a support structure and an attachment structure. The attachment structure is the part of the system to which 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.

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.

- A dynamically height adjustable crane
- A 1D force sensor for measuring the remaining weight lifted by the crane
- Weights (by default 150 kg), including a robust attachment for lifting these weights by the RACA robot*
- Optional: A 1D tensile force sensor for measuring the weight support applied by the RACA robot*
- A data acquisition system that captures the data from the 1D force sensor(s), at a minimum sample rate of 50 Hz

4.2 Method

Weights that are robustly attached to the crane. The weights are then also attached to the RACA robot* via the intended attachment point(s). Optionally a 1D force sensor can be inserted in this attachment to measure the pulling force applied by the RACA robot*.

By measuring the weight support provided by the crane (via the 1D force platform), and optionally also by a 1D force sensor in between the weights and the RACA robot*, the weight support levels can be validated.

The movement pattern of the weight, controlled by the crane, shall resemble the vertical translation of a patients COM* during normal use, within a pre-described ROM*. This ROM* should not exceed ranges specified by the manufacturer, nor should the downward speed of movement exceed the maximum movement velocity during normal use. Exceeding these values might trigger a falls protection safety function of the RACA robot*, which is not the safety skill validated using this protocol.

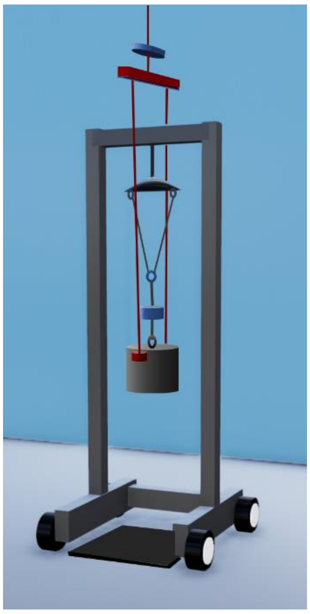

Figure 2: Structure of the test arrangement –the force sensors shown in blue, the crane in red

Sensor data from the force measurements should be recorded continuously to also track brief deviations from the target range due to possible timing issues in the dynamic situation.

Test full test sequence should be repeated at least 3 times to check for possible inconsistencies between sessions.

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.

For the dynamic height variations for each weight support level the height should be varied over the maximum range (as specified by the manufacturer or set in the system by the user) and at the maximum movement speed (as specified by the manufacturer or set in the system by the user).

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.

As is mentioned in paragraph 2.2, before starting the tests the allowable margins for the measured weight support have to be determined both for static and dynamic situations.

These margins, which are usually a percentage of the amount of the selected weight support, must be reported in the form from the Annex as $AllowedMargin_{Static}$ and $AllowedMargin_{Dynamic}$

The following sections includes instructions 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:

- Position the crane over of the RACA robot*and make sure no part of the crane setup will make direct contact with any part of the RACA robot*.
- Place the 1D tensile force sensor for measuring the remaining weight (not supported by the RACA robot*) in the crane attachment.
- Prepare the data acquisition system for recording the data from the 1D force sensor (s).
- 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.
- Connect the weights securely to the crane
    - Unless otherwise specified by the manufacturer, a minimum total mass of 150 kg[1] should be used.
- Lift the weight by the crane to the required height for the tests
- Prepare the dynamic height variations for the crane:

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

    - i.e. a predefined trajectory based on amount of movement and speed of movement, mimicking dynamic patient behavior during normal use. E.g. approximating the highest allowable movement range and/or movement velocity.
    - make sure a sequence of at least 30 full up and down movements is prepared
- Optionally attach a second 1D force sensor to the attachment points for the harness on the RACA robot*
    - Connect the second 1D force sensor to the data acquisition system
    - Make sure the second 1D force sensor is calibrated and sufficiently warmed up
    - Zero level the second 1D force sensor or record an offset level measurement for the output for the unloaded sensor.
- Attach the frame to the harness attachment points of the RACA robot* (optionally via the second 1D force sensor), using a method that is well suited to carry the required weights during the tests.

5.2.2 System Conditions

- Make sure the system is started and prepared for normal use as described in the user manual

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.

Test for at least 3 different weight support levels for performing the tests: one in the 10-30%, one in the 31-70% and one in the 71-100% weight support range

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 the Annex.

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 harness attachment point of the RACA robot*
- [step 2] Check there is no slack in the connection between the harness attachment points and the frame with the weights
- [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] Optionally set the allowable ROM* for the vertical motion
- [step 8] Start the weight support function of the RACA robot*
- [step 9] Keep the crane static for 10 seconds
- [step 10] Start the prepared sequence of movement by the crane
- [step 11] Stop the prepared movement sequence when sufficient movements are completed
- [step 12] Keep the crane static 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 released in a controlled way
- [step 14] Move the support platform up to make sure the weight is only supported by the platform

- [step 15] Keep the setup stationary for 5 seconds
- [step 16] Stop the data acquisition system
- [step 17] Repeat this test 3 times
- [step 18] Disconnect the attachment from the weight to the harness attachment points

5.4 Data Analysis

- Data of the 1D force sensor(s) can be filtered using a 10 Hz zero phase low pass filter.
- When using the 1D force sensor in the weight support attachment of the RACA robot*, the weight of this 1D force sensor should be included in the calculations to compensate for this weight.
- The first and last 5 seconds of the recorded data from the load cell should display the weight of the fully supported mass. This measured weight ($MeasuredWeight_{Total}$) will be used in the calculations
- In the 10 second intervals, where the weight is partially supported by the RACA robot*, the data of the load cell provides the remainder of the total mass minus that is still supported by the support platform.
    - Optionally: the output of the 1D force sensor shows the force used during weight support
- During the interval where the movements of the support platform are applied the data of the load cell provides the value of the total mass minus the support level provided by the RACA robot*.
    - Optionally: the output of the 1D force sensor shows the force used during weight support

The actual support level can be calculated by

$$F_{WeightSupportMeasured} = MeasuredWeight_{Total} - F_{LoadCell}$$

The test is considered as a pass:

- when during both the static phases of the weight support by the RACA robot* results in:

$$F_{WeightSupportMeasured} = F_{SetWeightSupport} \pm AllowedMargin_{Static}$$

AND

- when during the dynamic phase of the weight support by the RACA robot* results in:

$$F_{WeightSupportMeasured} = F_{SetWeightSupport} \pm AllowedMargin_{Dynamic}$$

5.5 Report

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

In this form the set weight support value, including allowable margins, need to be reported. Note the min and max target values for the static tests and the dynamic test for each of the test sequences.

For each test sequence the weight of the total mass used as measured by the load cell at the start and the end of the test sequence must be recorded.

Report the measured min and max weight support values for both the static weight support phases in each of the test sequences, as well as the measured min and max weight support values during the dynamic weight support phases.

Note that, for brevity, in the report tables this $F_{WeightSupportMeasured}$ is named $F_{WeightSupport}$.

Report a PASS when all measured values are within the allowed range. Otherwise report a FAIL.

The conclusion is a PASS when all items above were a PASS, otherwise it is a FAIL.

6 Bibliography

EN IEC 60601-1: 2006

EN IEC 80601-2-78:2020

Annex A: Test form

Test form protocol WSU-LRE-2			
Test date		Name of tester	
Sequence ID			
RACA robot* under test (name and type)			
RACA robot* SN			
Crane used: Model		SN	
Force sensor used		Type	
Calibration date		SN	
Optional 1D force sensor used		Type	
Calibration date		SN	
1D forcesensor weight			
Total weight used			
Support level set			
Allowed $Margin_{Static}$			
Allowed $Margin_{Dynamic}$			
	Value	Target Min	Target Max
Target $F_{WeightSupport}$			
Test condition			

Test sequence #1					
	Avg + StDev	Min	Max	Target min/max	PASS/FAIL
$F_{LoadCell}$ during first full weight support via load cell (AVG and StDev)					
$F_{LoadCell}$ during second full weight support via load cell (AVG and StDev)					
$F_{WeightSupport}$ during first static weight support phase (min/max)					PASS/FAIL
$F_{WeightSupport}$ during second static partial weight support phase (min / max)					PASS/FAIL
$F_{WeightSupport}$ during dynamic partial weight support phase (min / max)					PASS/FAIL

Test sequence #2					
	Avg + StDev	Min	Max	Target min/max	PASS/FAIL
$F_{LoadCell}$ during first full weight support via load cell (AVG and StDev)					
$F_{LoadCell}$ during second full weight support via load cell (AVG and StDev)					
$F_{WeightSupport}$ during first static weight support phase (min/max)					PASS/FAIL
$F_{WeightSupport}$ during second static partial weight support phase (min / max)					PASS/FAIL
$F_{WeightSupport}$ during dynamic partial weight support phase (min / max)					PASS/FAIL

Test sequence #3					
	Avg + StDev	Min	Max	Target min/max	PASS/FAIL
$F_{LoadCell}$ during first full weight support via load cell (AVG and StDev)					
$F_{LoadCell}$ during second full weight support via load cell (AVG and StDev)					
$F_{WeightSupport}$ during first static weight support phase (min/max)					PASS/FAIL
$F_{WeightSupport}$ during second static partial weight support phase (min / max)					PASS/FAIL
$F_{WeightSupport}$ during dynamic partial weight support phase (min / max)					PASS/FAIL
Conclusion:					**PASS/FAIL**

Final Information about test

Date of testing	
Name of tester	
Overall conclusion	
Signature	