Being safe around collaborative and versatile robots in shared spaces

Protocol

Test Exoskeleton for Single Axis Rotation Beyond Pre-Set Limits for Individual Patient Movement

EXO-LRM-1

The purpose of the protocol is to validate the safety skill "limit range of movement" for an angular motion of a single joint of an exoskeleton or a restrained-type rehabilitation robot. The range of motion is measured using an electro-goniometer.

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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1 Introduction

The purpose of this protocol is to validate the safety skill “limit range of movement“ for single axis rotations, which means that the robot is able to prevent a single axis rotation of a joint of an exoskeleton* type RACA* robot to be outside the angular range of motion (ROM), so it remains with the user’s physiological capabilities (as determined by the health practitioner). This protocol applies for both monocentric* as well as polycentric* joints.

Figure 1: Exemplary application of a single axis rotation (in this case between the upper arm and the forearm)

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	limit range of movement – for single axis rotation
System (device type)	exoskeleton
Sub-System	-
Domain	healthcare
Environment/condition	-
Measurement Device(s)	Electro-goniometer or comparable device

This protocol is not applicable for ROM limitation settings that can dynamically change, due to functionality of the robot. So this protocol is not applicable in situations where, for instance in a lower limb exoskeleton*, the knee joint may allow more flexion during swing phase, while during stance phase this angular ROM is restricted to provide the user with support to remain upright.

⚠	**Warning**
	This protocol only serves to support users by validating the effectiveness of a skill which the integrator of the system applied as technical measures to reduce the risk of one potentially hazardous situation. This means that the use this protocol requires the prior execution of a proper and complete risk assessment, which also serves as a source of a test situation and conditions.

1.2 Definitions and Terms

Exoskeleton (source: COST Action CA16116 (to be published)) wearable, multi-segment structure, working in parallel with the human body, that enables, assists, and/or augments motion and/or posture (COST Action CA16116 (to be published))

Monocentric joint (source: ISO 13405-2 – clause 6.3.3)

The axis of rotation is constant for all angles of flexion

Polycentric joint (source: ISO 13405-2 – clause 6.3.3)

The axis of rotation changes with the angle of flexion

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

Medical robot intended to perform Rehabilitation, Assessment, Compensation or Alleviation comprising an actuated applied part (IEC 80601-2-78 – clause 201.3.212)

Rehabilitation robot

See RACA robot

ROM (source: local to the document)

Range of Motion

2 Concept and Objectives

2.1 Hazardous Situation

Single axis exoskeletons can be used to facilitate movements of the limb round that joint. These robotic joints are often powered and can either be fully controlled by the robot controller (e.g. to be used for mobilizing a joint) or controlled by the person wearing the device, where the robot is used to support or enhance movements. In this latter case the robot can be used during rehabilitation exercises or as an assistive device during daily life activities.

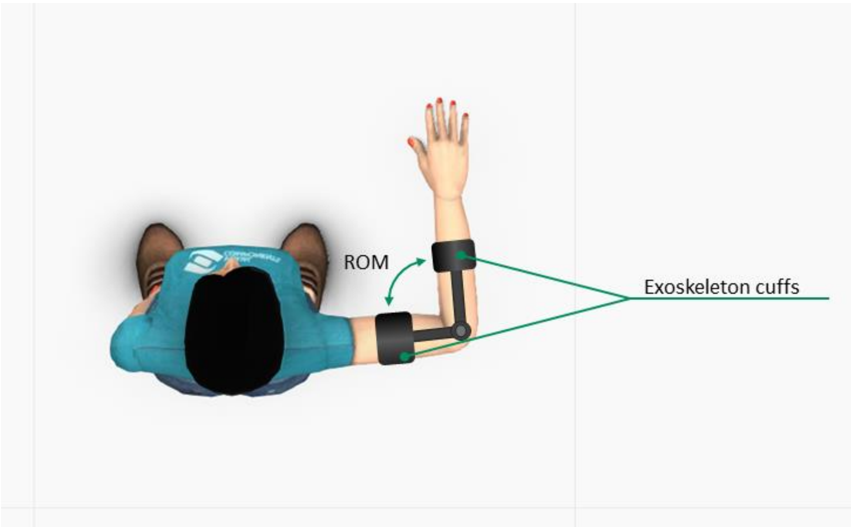

Figure 2: Exemplary application of a single axis rotation with a pre-defined ROM

Hazardous situations related to single axis flexion/extension movements can be:

- Physical damage to a joint or limb segment due to crossing biomechanical limits (like hyper extension).
- Pain complaints in the subject due to over-flexing or over-extending of the joint.

2.2 Target behavior and Metrics of the Safety Skill

The target behavior of the safety skill to be validated is to prevent the single axis hinge either to over-flex of over-extend outside either absolute limits (e.g. 0 degrees (anatomical reference angles) to avoid hyperextension) or outside limits, consisting of a maximum flexion angle and a maximum extension angle, set by a user possibly for an individual subject.

For validating the robot skill "Limit range of movement" for single axis rotations, the output targets are:

- Maximum flexion angle [deg] in relation to the set/predefined maximum flexion angle
- Maximum extension angle [deg] in relation to the set/predefined maximum extension angle

The values for the target metric should be determined during or according to the risk assessment. For this validation protocol, the target metrics are pass or fail criteria of the mentioned output quantities:

- Remains within the defined maximal flexion angle (TRUE/FALSE)
- Remains within the defined maximal extension angle (TRUE/FALSE)

Please report the values of the target metric for each test using the form in the Annex.

Figure 3: Anatomical neutral position

Note: The definition of 0 degrees may differ between clinical users and (technical) developers. For clinical users 0 degrees usually is the angle between 2 segments relative to each other in the anatomical neutral position.

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 in the Annex.

Note: This protocol only serves to support users by validating the effectiveness of a skill which the integrator of the system applied as technical measures to reduce the risk of one potentially hazardous situation. Beware that the skill may be influenced by the occurrence of a single fault condition. If applicable, make sure also to test under that single fault condition.

3.1 System

The speed of the flexion motion in combination with the applied load to the robot arm may affect whether the safety skill remains valid. Also, due to the inertia also the length of the robot segments may influence this safety skill. Therefore, the skill should be validated:

- At maximum speed/angular velocity as specified by the manufacturer
- With maximum load as specified by the manufacturer
- With maximum segment lengths as specified by the manufacturer.
- At planes of motion which represent worst case situations within the specifications of the manufacturer

If the user can change the ROM limit settings, the tests should also be repeated using at least 3 different ROM settings, e.g. a minimum, maximum and medium range setting, which would cover/represent the range of ROM settings.

In a static position a load can also influence the skill. Therefore also the static behavior should be validated:

- With a maximum load as specified by the manufacturer
- With maximum segment lengths as specified by the manufacturer.
- In a plane of motion which represent worst-case situations within the specifications of the manufacturer

The "fixed"/proximal segment of the 2 segments can be considered as a subsystem of this hinge joint. During normal operation of such a robot, movement of the complete system might add some inertia to the distal segment. Sudden directional changes of the proximal segment may influence flexion behavior at the hinge joint significantly. If this could occur tests should be performed at an angular velocity that would be similar to an angular velocity that may result from the sudden directional change of the proximal segment.

3.2 Environment

When the safety skill for the robot joint is specified to function during movements in different planes, the validation should be performed during flexion experiments in worst case planar situations.

E.g. movements need to be applied with a fully loaded flexion and in a plane (inside the specified working range) with maximal gravitational influence or variation of this influence as well as in a plane with minimal gravitational influence.

When, according to the risk assessment the safety skill for the robot joint could perform differently under different normal use conditions, the skill should be validated in environments that resemble these normal use conditions.

4 Setup

4.1 Equipment

To measure the actual angles the hinge joint makes, the following sensor will be used:

- Electro-goniometer, or a physical joint simulator, or (for simple hinge joints) an optical rotary encoder– combined with computer and data acquisition software.

With these sensors the angle between 2 segments can be measured. Special attention should be given to:

- The sensor should be attached to the robot in such a way that no movement between the sensor and the robot is possible. This requirement may have implications on the choice of the type of electro-goniometer to be used.
- The fact that the zero angle reading of these sensors may differ slightly from those used by the robot due to a set misalignment of the sensor segments with respect to the robot segments. To correct for this an offset measurement should be performed when the robot segments are set under a known angle relative to each other.

4.2 Method

The angle sensor will be mounted on the robot so the ROM can be measured reliably (see Figure 4).

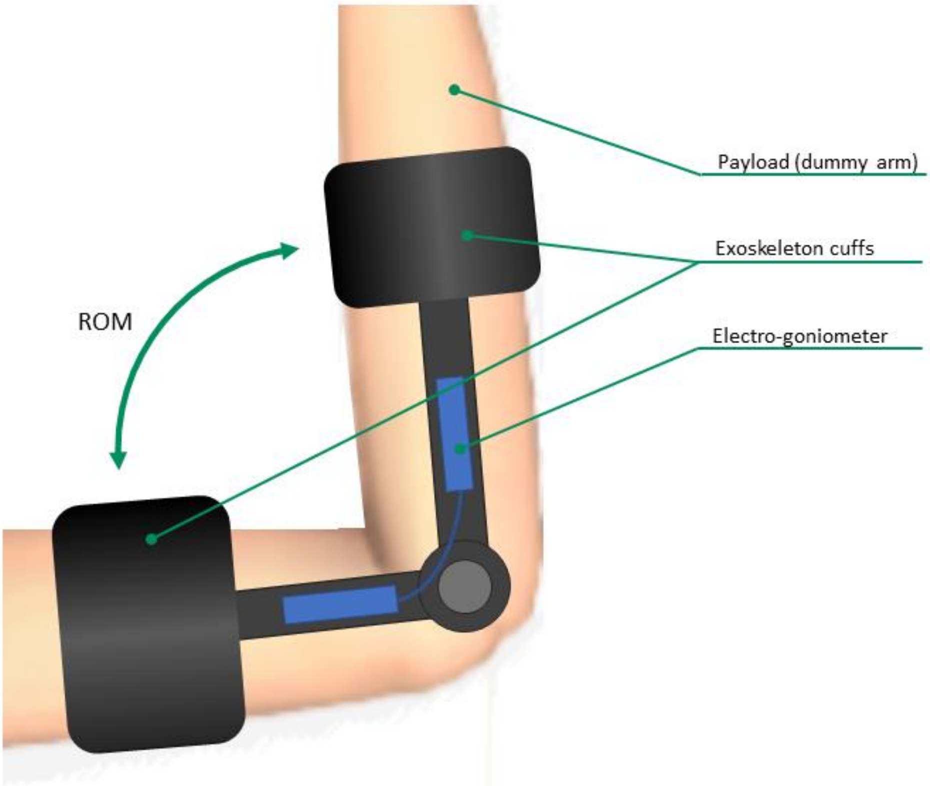

Figure 4: Isolated view of a test setup measuring the angular ROM

Data should be recorded at a recording rate that allows a proper recording at the required maximum angular velocity. As a rule of thumb a recording rate which can capture at least 1 degree movements during maximum angular velocity can be used.

Data smoothing can be performed, but the filtering frequency should be about 10 times larger than the highest frequency in the motion, to make sure that no significant change is made to the min/max values of the measurement values.

5 Procedure

5.1 Test Plan

Test the setup in a worst-case situation that can happen during normal use.

- This worst case situation will be most likely during a test with the maximum payload as well as at the maximum angular velocity during angular movements, so:
  - Specify the angular velocity under which the test is performed
  - Specify the planes for which the test is performed
  - Specify the payload under which the test is performed
- Another case that has to be considered is the situation of a “long term” static load at the maximum flexion or extension angle. For this the following parameters should be specified
  - Specify the plane for which the test is performed
  - Specify the payload under which the test is performed
  - Specify the duration during which the test is performed

5.2 Preparation

5.2.1 Test Arrangement

Prepare the validation setup by following the steps described below.

- Position the robot in such a way that the motion of the hinge joint under test cannot be influenced by any nearby objects
- Make sure the robot is positioned in a normal use manner.
- Attach the payload to the robot, following instructions from the manufacturer. The payload should be in a form that resembles the normal use situation as closely as possible
- Attach the electro-goniometer to the robot, with the electro-goniometer aligned with the robot as accurately as possible.
- And prepare the measurement system

5.2.2 System Conditions

- Note the hardware configuration (angular ROM limits)
- Note the software configuration (set angular ROM limits, speed limitations)
- Note the segment lengths for both the proximal and the distal segment
- Note under which angular velocity the test is conducted
- Note the payload under use
- Note the location of the payload
- Note whether the test is performed under normal conditions or under single fault condition.

5.2.3 Environmental Conditions

- When applicable, note the use condition for which the safety skill is validated.

5.3 Test Execution

Sensor offset detection

- Make sure the sensor is attached firmly to the robot and as well aligned as possible

- Instruct the robot to move the hinge joint to a defined angle
- Measure this angle with the electro-goniometer – document the difference between the measured angle and the angle set by the robot. This angle difference should not exceed ± 2 degrees.

Static test

- Setup the robot joint system at the maximum flexion angle in a specified worst-case situation.
- Attach the payload to the normal location at the robot arm
- Start the data acquisition
- Acquire data for at least the minimum number of seconds the system is specified to maintain this angle under the specified payload.
- Repeat previous steps for other safety critical situations

Dynamic test

- Position the robot arm in a worst-case orientation that could happen during normal use. This may be the horizontal plane or a plane where gravitational influence is maximal
    - Attach the payload to the normal location at the robot arm
    - Set the flexion/extension boundaries in the robot system.
    - Start the data acquisition
    - Instruct the robot to move at the specified maximum angular velocity back and forth over the specified angular range of motion
    - Repeat this 10 times
- Repeat the previous steps for other safety critical situations

5.4 Data Analysis

Before interpreting the data to determine whether the test was passed, the values measured by the electro-goniometer should be filtered using a moving average filter with a window width of 50 ms, to avoid that system noise peak values could cause the robot to fail the test.

When the measurement values do not exceed the specified angular limits (plus the accuracy of the electro goniometer) during a single measurement, it passes that individual measurement.

5.5 Report

Use the form in Annex I to register the results of the various measurements

6 Annexes

A Report Form for Dynamic Situation

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

Target metrics (dynamic test)				
Target max flexion angle (deg)				
Target min flexion angle (deg)				
Testing conditions				
Length proximal segment (mm)			PayLoad (kg)	
Length distal segment (mm)			Payload location	
Max Angular velocity (deg/sec)				
Environmental condition:				
Single fault condition		Yes/No :		
Test results				
TrialNr	Plane of motion minimum / maximum gravitational influence		Measured angular velocity (deg/sec)	Pass/no pass

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B Report Form for Static Situation

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

Target metrics Static			
Starting angle (deg)			
Test duration (sec)			
Testing conditions			
Length proximal segment (mm)		PayLoad (kg)	
Length distal segment (mm)		Payload location	
Environmental condition:			
Single fault condition	Yes/No :		
Test results			

TrialNr	Plane of motion minimum / maximum gravitational influence	Angle range during test (deg)	End angle (deg)	Pass/no pass