Being safe around collaborative and versatile robots in shared spaces

Protocol

Assessment of the rehabilitation robot for the prevention of anatomical joint range of movement and anatomical joint overreaching risks for the subject – Human in (shared) control – testing with anthropometrically adjustable and sensorized dummy limb

(ROB-LAJRM-LAJO-1)

The purpose of this protocol is to validate the safety skill "limit anatomical joint range of movement" and "limit anatomical joint overreaching" for the patient's upper limb actuated by the RACA rehabilitation robot through one or more, either free or restrained connection points. Either arm type or exoskeleton type RACA rehabilitation robot can move that point or points within a 3D volume. The validation toolkit includes a measurement device: an anthropometrically adjustable and sensorised dummy limb which is attached to the RACA rehabilitation robot; and a software tool: an off-line risk assessment and reporting tool.

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

Project consortium

DANISH TECHNOLOGICAL INSTITUTE
Fraunhofer IFF
cea
Istituto di Tecnologie Industriali e Automazione
Consiglio Nazionale delle Ricerche
Roessingh Research and Development

Grant agreement no. 779966
Date 2018-04-13

Being safe around collaborative and versatile robots in shared spaces

CONTENTS

Being safe around collaborative and versatile robots in shared spaces

1 Introduction

A safe RACA rehabilitation robot must monitor and control online the patient's key therapeutic physiological parameters. Two of those parameters stem from the kinematics of the actuated single body parts and the actuated linkages comprising of body parts linked with anatomical joints. The purpose of this protocol is to validate the upper limb RACA rehabilitation robot's safety skills "limit patient's anatomical joint range of movement" and the "limit patient's anatomical joint overreaching".

During manual upper and lower limb physiotherapy, the therapist is responsible for interpreting and controlling the patient's physiological parameters in the joint reference coordinate systems. Such an approach can be observed when the physiotherapist is taking care of not exceeding anatomical joint range limits and not attaining pre-defined undesired anatomical joint postures. In addition, the physical rehabilitation therapy of the human motion system must be adapted to each patient's individual needs. Therefore, a RACA rehabilitation robot must monitor the movement of the anatomical joints varied from patient to patient. The primary harm defined in this protocol is that the RACA rehabilitation robot must not move any actuated anatomical joint over the pre-set lower and upper angle thresholds. The second harm defined in this protocol is that the RACA rehabilitation robot must not bring the anatomical joints synchronously to a pre-defined set of anatomical joint angles.

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill #1	limit anatomical joint range of movement
Skill #2	limit anatomical joint overreaching
System	Arm type of Exoskeleton type RACA robot for upper limbs
Sub-System #1	Support system for the RACA robot
Sub-System #2	Support system for the patient
Domain	Healthcare.
Conditions	The RACA robot moves one or more actuated applied parts of the upper limb in 3D.
Measurement Device(s)	An anthropometrically adjustable and sensorised dummy limb and an off-line risk assessment and reporting software tool

⚠	**Warning**
	This protocol supports users only to validate the effectiveness of the skills listed in the profile above. The skill should be a technical measure of the RACA robot system to mitigate the risk of one potentially hazardous situation as identified in the risk assessment. In general, the risk assessment is a mandatory and helpful source to identify test situations and conditions relevant for a proper validation.

1.2 Normative Reference

Before using this protocol, please make yourself familiar with the following regulations and standards referenced by this protocol:

IEC 80601-2-78:2019

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

1.3 Definitions and Terms

ACTUATED APPLIED PART (source: IEC 80601-2-78:2019 – clause 201.3.201)

subcategory of APPLIED PART that is intended to provide actively controlled physical interactions with the PATIENT that are related to the PATIENT's MOVEMENT FUNCTIONS, to perform a CLINICAL FUNCTION of a RACA ROBOT

ANATOMICAL JOINT RANGE OF MOTION (source: local to the document)

Range of motion for an anatomical joint. For example, according to the American Academy of Orthopedic Surgeons (AAOS), the range of motion for the elbow joint is between 0° and 150° for a healthy and adult human.

ANATOMICAL JOINT RANGE OF MOTION LIMIT (source: local to the document)

A pre-defined set of upper and lower boundary angle values for an anatomical joint. This value represents the extreme maximum and minimum values within the safe limit within which hazards are avoided. Anatomical joint range of motion limits can be equal to anatomical joint range values but usually, due to the physiology of the patient's disease, are a subset of the anatomical joint range.

ANATOMICAL JOINT OVERREACHING (source: local to the document)

It occurs when there is no relative angle between any neighboring body parts in the upper limb. Therefore, the upper limb is overreaching when the upper arm aligns fully with the lower arm, and the lower arm aligns fully with the hand. In terms of anatomical joint angles, the elbow flexion-extension angle is 0°, the wrist flexion-extension angle is 0°, and the ulnar-radial deviation angle is 0°.

ANATOMICAL JOINT OVERREACHING LIMIT (source: local to the document)

A pre-defined set of upper and lower boundary angle values with respect to the anatomical overreaching state. It represents the extreme maximum and minimum values within the safe limit within which hazards are avoided. Anatomical joint overreaching limits consider the physiology of the patient's disease. An example of the anatomical joint overreaching limits is the following set of anatomic angles: elbow flexion-extension: 1° - 0°, wrist flexion-extension: 2° - 2°, ulnar-radial deviation: 2° - 2°.

DEGREES OF FREEDOM (DOF) (source: local to the document)

The number of independent movements allowed to the body or, in the case of a mechanism made of several bodies, the number of possible independent relative movements between the links of the mechanism.

JOINT RANGE OF MOTION (source: local to the document)

The full movement potential of a rotational joint. Each rotational joint has its range of motion represented by the upper and lower boundary angle values.

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

MEDICAL ROBOT intended by its MANUFACTURER to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION comprising an ACTUATED APPLIED PART.

SENSORISED DUMMY UPPER LIMB (source: local to the document)

Plastic, hollow structure to emulate the human upper limb at both left and right sides and in the anthrompometric sizes ranging from 5%ile female to 95%ile male. It consists of the anatomical joints of the shoulder: 3 DOF spherical joint, the elbow: 1 DOF rotational joint, and the wrist: 3 DOF spherical joint. Rotational angle sensors are built into the dummy limb to measure the rotational angle of each anatomical joint.

2 Concept and Objectives

The upper limb in the biomechanics literature is modelled usually with a 7 DOF serial mechanism, where the shoulder joint is a spherical joint with three degrees of freedom, the elbow joint is a modified hinge with one degree of freedom, and the wrist joint is a spherical joint with three degrees of freedom[1]. The shoulder complex performs five degrees of freedom motion, but the anatomical motions of shoulder elevation-depression and shoulder protraction-retraction are not considered in this protocol. The rigid bodies in the upper limb biomechanical model are the upper arm, the lower arm, and the hand.

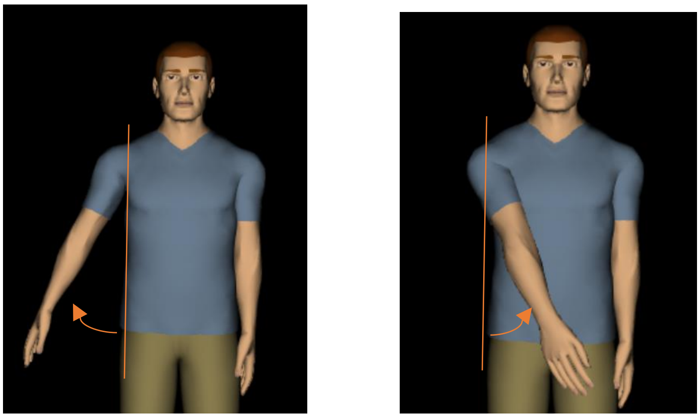
The anatomical joint ranges of motion are established based on a massive database of measurements done on healthy people. Therefore, anatomical joint ROMs vary from one establishing organisation to another with slight differences. The most prominent normative reference values are:

- NASA, Man-system integration standards (NASA-STD-3000), N.J.S. Centre, Editor. 1987: Houston, Texas, USA[2],
- Department of social & health services, Range of Joint Motion Evaluation Chart, Washington, USA[3],
- American Academy of Orthopaedic Surgeons (AAOS)[4],
- American medical association (AMA)[5].

2.1.1 Shoulder Joint

According to Kapandji[6], shoulder abduction is the movement of the upper limb away from the trunk and takes place in a coronal plane about an antero-posterior axis (Figure 1.a). Shoulder adduction, however, is the opposite movement of the upper limb toward the trunk only when it is combined with shoulder extension or flexion (Figure 1.b). According to AAOS, the max. anatomical joint ROMs are 180° and 30° for shoulder abduction and adduction, respectively.

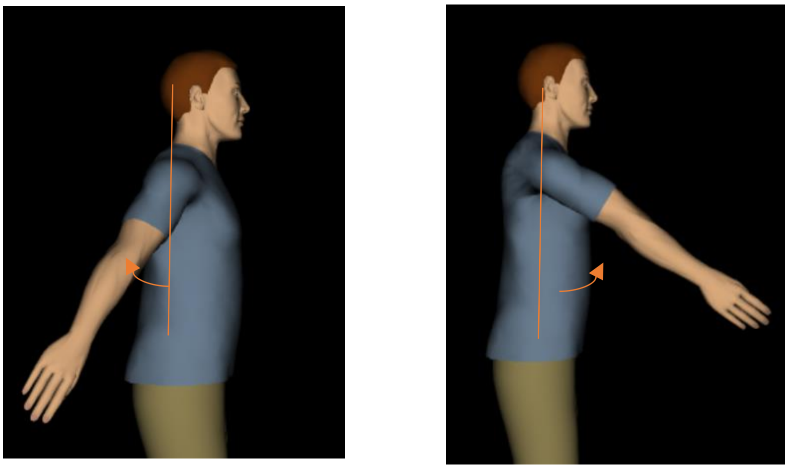
[1] Sheraz S. Malik: Orthopaedic Biomechanics Made Easy, Cambridge University Press, 2015
[2] https://msis.jsc.nasa.gov/sections/section03.htm
[3] https://www.dshs.wa.gov/sites/default/files/FSA/forms/pdf/13-585a.pdf
[4] https://www5.aaos.org/uploadedFiles/PreProduction/Quality/About_Quality/outcomes/AAOS%20Nor mative%20Data%20Study%20and%20Scoring.pdf
[5] https://ama-guides.ama-assn.org/newsletter/article-abstract/20/3/3/159/Range-of-Motion-AMA-Guides-Sixth-Edition?redirectedFrom=fulltext
[6] A. I. Kapandji: The Physiology of the Joints, volume one, Handspring Publishing Limited, 2019



a) b)

Figure 1: Shoulder abduction (a) and shoulder adduction (b)

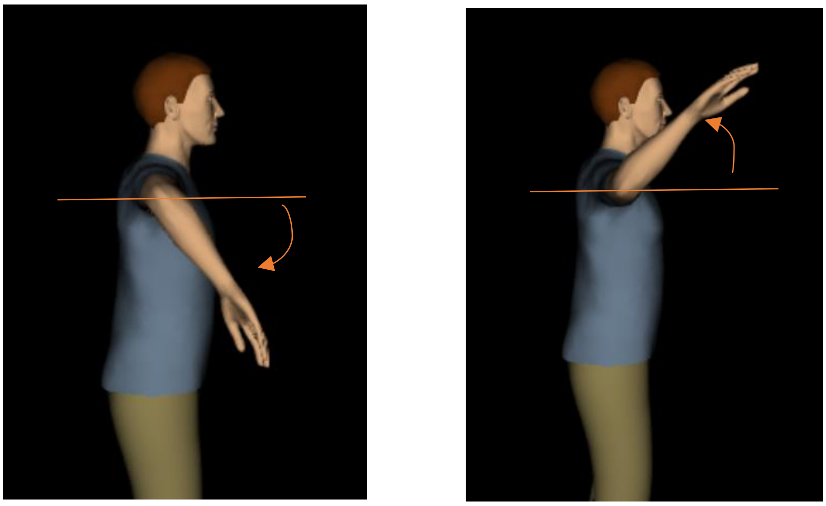
Shoulder flexion and extension (Figure 2) are the movements performed in a sagittal plane, about a transverse axis[6]. The maximum anatomical joint ROMs – according to AAOS – are 180° and 60° for shoulder flexion & extension, respectively.



a) b)

Figure 2: Shoulder flexion (a) and shoulder extension (b)

Shoulder external and internal rotation (shoulder lateral and medial rotation) (Figure 3) is known as the rotation of the upper arm around its longitudinal axis[6]. According to AAOS, the maximum anatomical joint ROMs are 90° and 70° for shoulder external rotation & internal rotation, respectively.

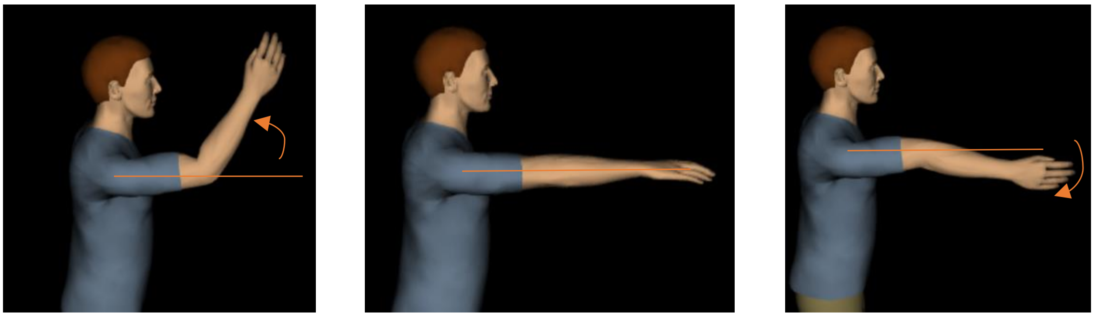


a) b)

Figure 3: Shoulder external rotation (a) and Shoulder internal rotation (b)

2.1.2 Elbow Joint

Elbow flexion (Figure 4.a) is the movement when the forearm moves towards the anterior surface of the arm[6]. Elbow extension (Figure 4.b) is the movement when the forearm moves towards the posterior surface of the arm. According to AAOS, the max. anatomic joint ROM for the elbow flexion is 150°, and for the elbow extension is 0°. However, for people with hyperextension capabilities, the elbow extension anatomic joint ROM can reach 10° (Figure 4.c).

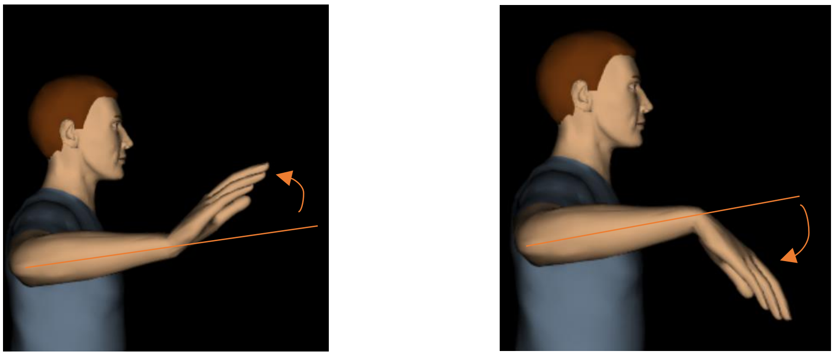


a) b) c)

Figure 4: Elbow flexion (a), Elbow extension (b) and Elbow hyperextension (c)

2.1.3 Wrist Joint

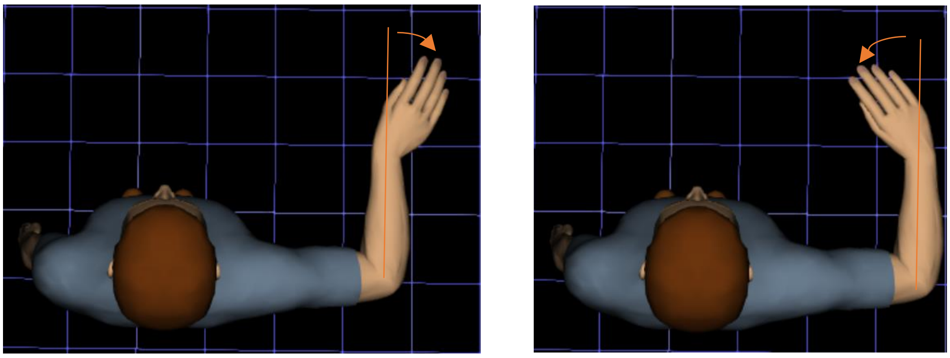
Wrist extension (Figure 5.a) is when the dorsal surface of the hand moves towards the posterior aspect of the forearm; wrist flexion (Figure 5.b) is the movement of the palmar surface of the hand towards the anterior part of the forearm[6]. According to AAOS, the maximum anatomical joint ROMs are 70° and 80° for wrist extension & flexion, respectively.



a) b)

Figure 5: Wrist extension (a), Wrist flexion (b)

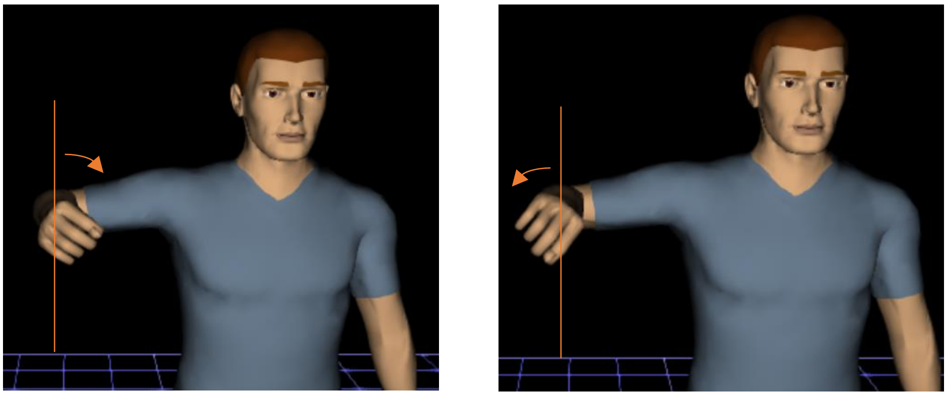
Wrist radial & ulnar deviations (Figure 6) are the movements of the hand away from the axis of the body and towards the axis of the body, respectively[6]. According to AAOS, the maximum anatomical joint ROMs are 20° and 30° for wrist radial & ulnar deviations, respectively.



a) b)

Figure 6: Wrist radial deviation (a), Wrist ulnar deviation (b)

Wrist pronation (Figure 7.a) is the hand's movement when the palm is facing inferiorly, and the thumb is pointing medially[6]. Wrist supination (Figure 7.b) is the movement of the hand when the palm is facing superiorly and the thumb is pointing laterally. According to AAOS, the maximum anatomical joint ROMs are 80° and 80° for wrist Pronation & Supination, respectively.



a) b)

Figure 7: Wrist pronation (a), Wrist supination (b)

2.2 Hazardous Situations

According to the Health and Safety Authority in Dublin, upper limb disorder could occur due to awkward postures[7] (Figure 8), leading to catastrophic hazards such a joint dislocation when the movement of the joint goes beyond the anatomical joint ROM limits.

Figure 8: Awkward upper limb postures

2.2.1 Anatomical Joint ROM Limit Hazard

Anatomical joint limit ROM hazard is a general term used when a particular anatomical joint reaches or exceeds the upper or lower thresholds of its ROM. The anatomical joints can experience seven different anatomical joint limit hazards within the selected kinematical model of the upper limb (Table 1)

Table 1: Classification of Anatomical Joint Limit Hazards and Zones.

Anatomical Joint limit hazard type	Range of motion[4]	Hazardous zone
Wrist Extension & Flexion limit hazard[8]	$[70°, -80°]$	ROM $\geq 70°$ or ROM $\leq -80°$
Wrist Radial & Ulnar Deviation limit hazard[8]	$[20°, -30°]$	ROM $\geq 20°$ or ROM $\leq -30°$
Wrist Pronation & Supination limit hazard[8]	$[80°, -80°]$	ROM $\geq 80°$ or ROM $\leq -80°$
Elbow Flexion & Extension limit hazard[8]	$[150°, -0°]$	ROM $\geq 150°$ or ROM $\leq -0°$
Shoulder Adduction & Abduction limit hazard[8]	$[180°, -30°]$	ROM $\geq 180°$ or ROM $\leq -30°$
Shoulder Flexion & Extension limit hazard[8]	$[180°, -60°]$	ROM $\geq 180°$ or ROM $\leq -60°$
Shoulder External & Internal rotation limit hazard[8]	$[90°, -70°]$	ROM $\geq 90°$ or ROM $\leq -70°$

[7] https://www.hsa.ie/eng/Publications_and_Forms/Publications/Manual_Handling_and_Musculoskeletal_Disorders/Guide_on_Prevention_and_Management_of_Musculoskeletal_Disorders_MSDs_.pdf
[8] ROM values are transformed into negative numbers.

2.2.2 Anatomical Joint Overreaching Hazard

Overreaching posture, in general, is referred to when a person attempts to reach a position outside the upper limb's workspace to perform a task. In our approach, anatomical joint overreaching hazard occurs only when anatomical joint limit hazard is not present. Due to the nature of the upper limb kinematics, the anatomical joint overreaching risk may occur only at the outside perimeter of the upper limb's workspace(Figure 9).

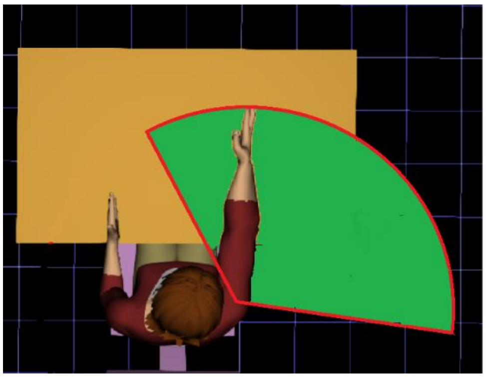


Figure 9: An example of the right-hand anatomical joint overreaching hazard

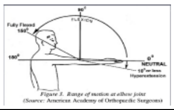
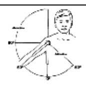
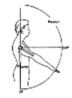
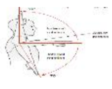
2.3 Target Behaviors and Metrics of the Safety Skills

The current protocol defines two hazardous situations, thus the target behaviors and metrics of the safety skills are described separately.

2.3.1 The Target Behavior and Metrics of the Safety Skill #1: Limit Anatomical Joint Range of Movement

For anatomical joint limit risk analysis, the user of this protocol needs first to specify the anatomical joint limit values for each joint ROMs (Table 1). The upper and the lower limit start angles vary among patients according to their disease, therapeutic progress status, age, and other personal characteristics. After entering the individual upper limit and lower limit start angles into the risk zone table (Table 2), the user of this protocol defines the percentage of the Take Care zone over the anatomical joint ROMs. This way, we introduce three different risk zones for each anatomical joint movement ROM in Table 2: the Red zone is the Prohibited zone, the Orange zone is the Take Care zone, and the Green zone is the Riskless zone. The Prohibited zone is when the anatomical joint is experiencing a hazardous posture that cannot be allowed during manual or robot-assisted therapy. The Take Care zone is when the anatomical joint moves near a hazardous posture determined by the previously defined percentage factor. The Riskless zone refers to safe movement without any danger.

Table 2: Definition of risk zones for anatomical joint limit risk

Joint	Motion type	Illustration	Range of Motion	Prohibited Zone upper limit start angle [degree]	Take Care Zone upper limit start angle [degree]	Riskless Zone [degree] from - to		Take Care Zone lower limit start angle [degree]	Prohibited Zone lower limit start angle (degree)	Percentage of take care zone
Wrist	Extension & Flexion		150	70	62.5	62.5	-72.5	-72.5	-80	5%
	Radial & Ulnar Deviation		50	20	17.5	17.5	-27.5	-27.5	-30	5%
	Pronation & Supination		160	80	72	72	-72	-72	-80	5%
Elbow	Flexion & Extension		150	150	142.5	142.5	7.5	7.5	0	5%
Shoulder	Adduction & Abduction		210	180	169.5	169.5	-19.5	-19.5	-30	5%
	Flexion & Extension		240	180	168	168	-48	-48	-60	5%
	External & Internal rotation		160	90	82	82	-62	-62	-70	5%

For this validation protocol, the target metrics of the Safety Skill #2: Limit Anatomical Joint Range of Movement are:

- Does any and if so, which of the shoulder, elbow, and wrist anatomical joints move in the Prohibited anatomical joint ROM zones? (Yes/No, list of anatomical joint motion type)
- The rate of anatomical joints movement duration in the Prohibited zone over the entire therapeutic movement duration. (%)
- Does any and if so, which of the shoulder, elbow, and wrist anatomical joints move in the Take Care anatomical joint ROM zones? (Yes/No, list of anatomical joint motion type)
- The rate of anatomical joints movement duration in the Take care zone over the entire therapeutic movement duration. (%)

Please report the values of the target metrics for each test using the form in Annex 6.1 Report form.

2.3.2 The Target Behavior and Metrics of the Safety Skill #2: Limit Anatomical Joint Overreaching

In terms of anatomical joint angles, the anatomical joint overreaching risk occurs at the simultaneous incidence of the following conditions:

- The elbow is fully extended (elbow flexion=0°, elbow extension=0°),
- The wrist is fully extended (wrist extension=0° , wrist flexion=0°, radial deviation=0°, ulnar deviation=0°)

The user of this protocol enters the individual upper limit and lower limit start angles into the risk zone table (Table 3) to define the thresholds of the Take Care zone of the anatomical joint overreaching risk. This way, we introduce two different risk zones for the anatomical joint overreaching risk: the Red zone is the Prohibited zone, and the Orange zone is the Take Care zone. Upper limb postures represented different angles than those of the Prohibited zone or the Take Care zone are considered riskless in terms of the anatomical joint overreaching risk.

Table 3: Definition of risk zones for anatomical joint overreaching limit risk

# Overreaching Risk	Only if the three anatomical joint angles are simultaneously in these ranges!	Take care zone range [degree]		Prohibited angle [degree]
wrist	Extension & Flexion	7.5	-7.5	0
	Radial & Ulnar Deviation	2.5	-2.5	0
elbow	Extension & Flexion	7.5	-7.5	0

For this validation protocol, the target metrics of the Safety Skill #2: Limit Anatomical Joint Overreaching are:

- Does the upper limb move in the Prohibited Anatomical Joint Overreaching posture? (Yes/No)
- The rate of the Prohibited Anatomical Joint Overreaching movement duration over the entire therapeutic movement duration. (%)
- Does the upper limb move in the Take Care Anatomical Joint Overreaching zones? (Yes/No)
- The rate of Anatomical Joint Overreaching movement duration in the Take care zone over the entire therapeutic movement duration. (%)

Please report the values of the target metrics for each test using the form in Annex 6.1 Report form.

NOTE!

A number of valid upper limb physiotherapy exercises, such as circling the extended arm around the shoulder, feature permanent overreaching risks!

3 Conditions

To assess the anatomical joint range of movement and anatomical joint overreaching risks with this protocol, it is valid under any conditions in which a RACA robot moves one or more actuated applied parts of the upper limb in 3D.

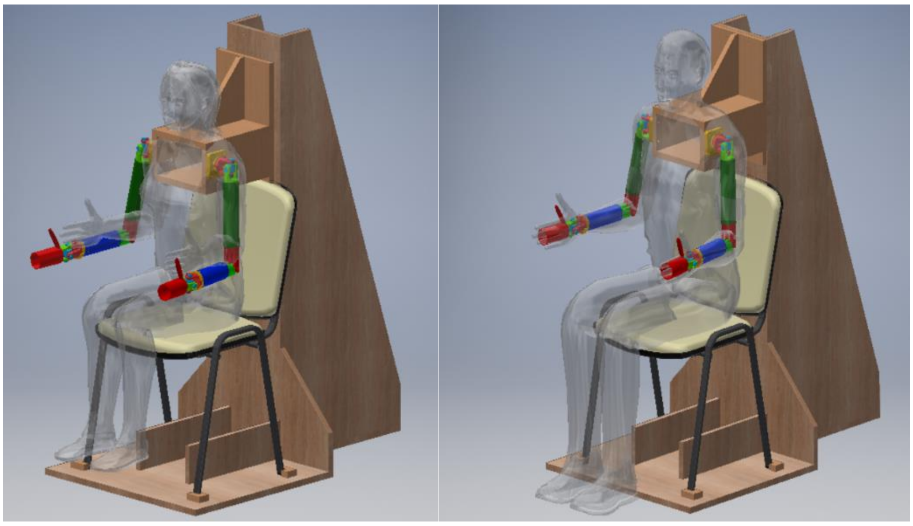
4 Setup

4.1 Test Arrangement

The testing device used in this protocol is an artificial dummy upper limb equipped with seven rotational angle encoders in the shoulder, elbow, wrist joints, and a supporting stand. The structure and design of the dummy upper limb and the stand (Figure 10, Figure 11) meet the following specifications:

- testing in sitting posture (with alteration of the stand, a lying posture setup is also feasible),
- mounting places on the stand for the left arm and right arm therapy,
- shoulder's height adjustability in the range between 5%ile female and 95%ile male anatomical sizes,
- upper and lower arms' lengths adjustability in the range between 5%ile female and 95%ile male anatomical sizes,
- three mechanical joints at the shoulder, at the elbow, and at the wrist with three, one, and three independent degrees of freedom, respectively,

- rotational angle sensor built-in in each anatomical joint.



a) b)

Figure 10: Dummy limb's side and shoulder height adjustability at 5%ile female (a) and 95%ile male

Figure 11: Left: 3D CAD rendered image of the dummy limb test rig (upper arm's length: 5%ile female, lower arm's length: 95%ile male); Middle: photo of the developed dummy limb test rig (upper arm's length: 95%ile male, lower arm's length: 5%ile female); Right: orange-black dummy limb prototype (upper arm's length: 95%ile male, lower arm's length: 95%ile male), white dummy limb prototype (upper arm's length: intermediate size, lower arm's length: intermediate size)

4.2 Sensing and other devices

To facilitate seamless and accurate risk assessment tests, the artificial dummy upper limb features several advanced technical solutions:

- the structure is 3D printed,
- rolling bearings in the anatomic joints (No.31 and No.32 in Figure 12),
- inner and outer aluminum bushings (No.4, No.5, No.17, and No.18 in Figure 12),
- hidden cable routing to all rotary sensors (No.26 in Figure 12) and the signal processing unit,
- spring pre-loaded latches (No.15 in Figure 12) for easy arm length adjustment,
- brake plugs (No.23 in Figure 12) for safe transportation and accurate zero offset calibration,
- push buttons (No.27 in Figure 12) for easy left-right side setting.

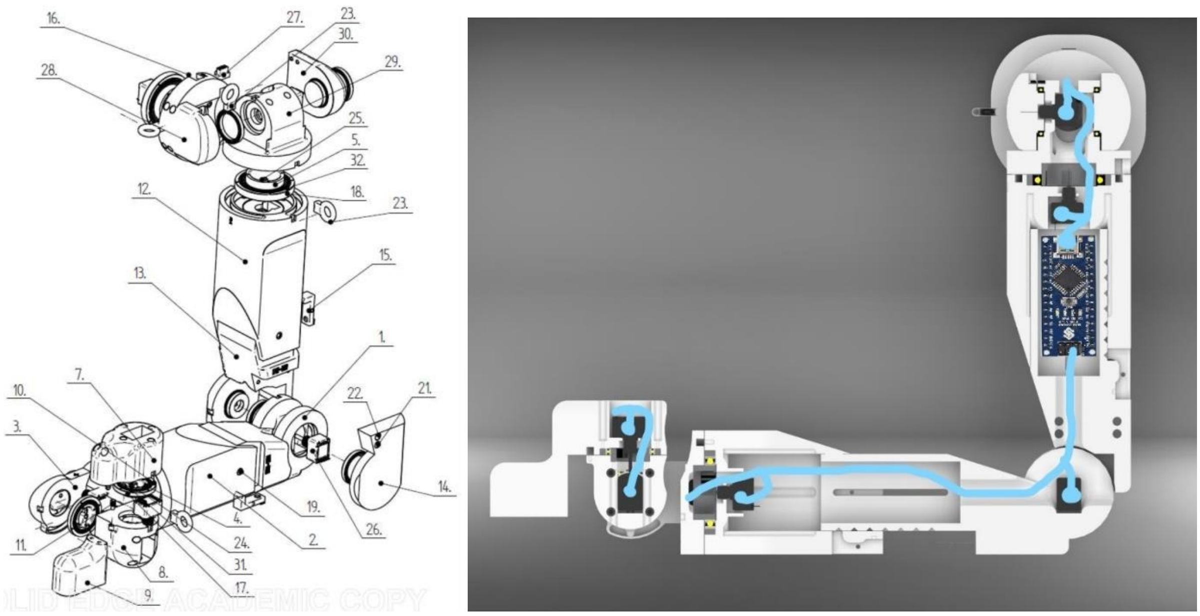


Figure 12: Left: exploded 3D assembly drawing of the dummy upper limb; Right: cross-sectional view of the dummy upper limb with the sensor data processing microcontroller board

4.3 Data Acquisition

The signal processing microcontroller unit reads the data of the rotational joint encoder sensors using a Daisy-Chain SPI communication protocol. A PC program then reads the measured data via a USB port with 10-bit resolution and at a rate from 1 Hz to 5000 Hz. The PC program can then log the data into a Comma-Separated Values (CSV) file format.

5 Procedure

5.1 Test Plan

Movement therapy of the upper limb can be either a continuous passive motion exercise free in the workspace or active-assisted motion restricted to a region of the workspace (Figure 13). The latter is often related to an Activity of Daily Living exercise.

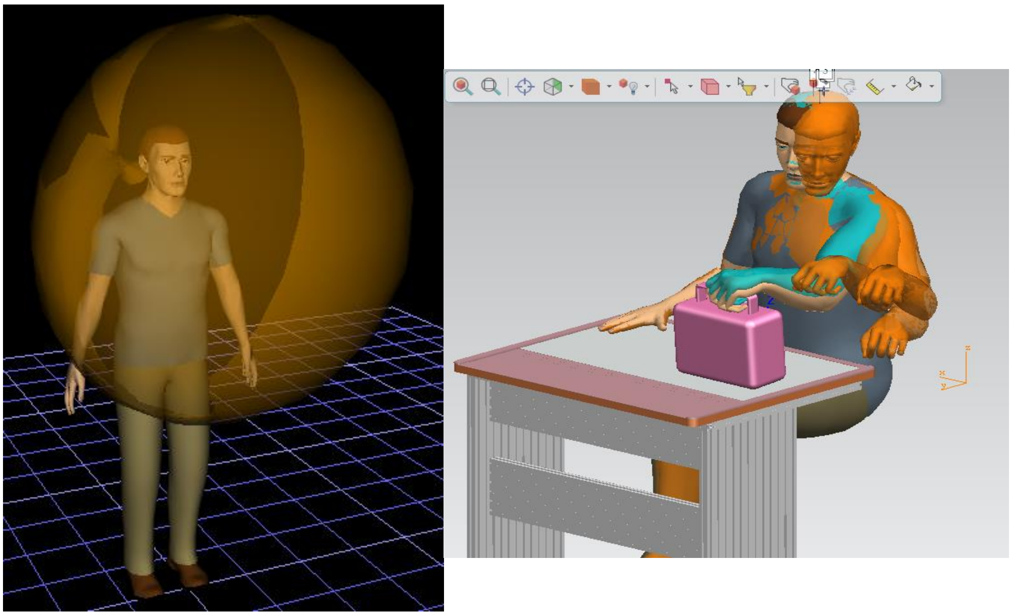


Figure 13: Left: workspace of the free passive motion of the left upper limb; Right: lifting-up a bag as an example for active-assisted Activity of Daily Living exercise

The testing system fostered in this protocol is intended for testing all the relevant upper limb RACA robot operations without particular preparations for the different test cases. Figure 14 shows the test plan that is valid for all test conditions.

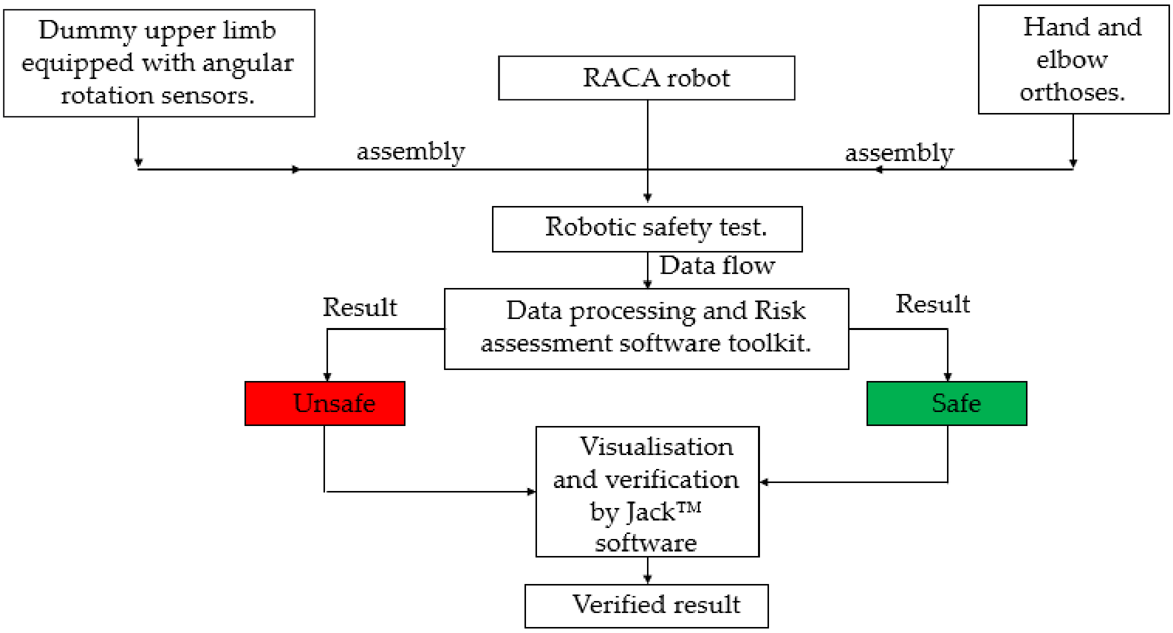


Figure 14: Flow chart of the ROB-LAJRM-LAJO-1 test

NOTE!

The user of this protocol may opt for visual verification of the risk postures in an ergonomics analysis and simulation tool equipped with Mocap (Motion Capture) data interface. Navigation functions of such ergonomics analysis and simulation tools allow the user to jump and visually check each frame marked with a risk. The authors of this protocol have developed a data interface on Sheet 3 of the Data processing and Risk assessment software toolkit (See chapter 5.4 Data Analysis) for the SIEMENS Tecnomatix Jack^{TM} 8.4 software tool.

5.2 Preparation

The user of this protocol prepares the anatomical size, the anatomical position, and the side of the dummy upper limb as follows:

1. Disengage the spring pre-loaded latch on the upper arm of the dummy upper limb (No.15 in Figure 12)
2. Set the telescopic length of the upper arm to the required anatomical size
3. Engage the spring pre-loaded latch on the upper arm of the dummy upper limb
4. Disengage the spring pre-loaded latch on the lower arm of the dummy upper limb(crossing the pointing line of No.2 in Figure 12)
5. Set the telescopic length of the lower arm to the required anatomical size
6. Engage the spring pre-loaded latch on the lower arm of the dummy upper limb
7. Loosen the screws between the shoulder enclosure and the stand
8. Set the shoulder enclosure to the required anatomical shoulder height
9. Fasten the screws between the shoulder enclosure and the stand
10. Operate the push buttons (No.27 in Figure 12) for setting the left-right sides of the dummy upper limb
11. Mount the dummy upper limb on the left or right mounting place of the shoulder enclosure by fastening the screws
12. Put the orthoses onto the dummy upper limb

5.2.1 Setup

The user of this protocol sets up the dummy upper limb for the test as follows:

1. Switch on the test PC with Windows Operation System
2. Launch a Continuously Updating, High-Resolution Time Provider for Windows on the test PC and for the controller of the RACA robot
3. Connect the dummy limb to the test PC with the USB cable
4. Launch the microcontroller program to read the signals of the rotational angle encoders
5. Launch the PC test program to read the rotational angle data from the microcontroller
6. Calibrate the dummy upper limb (zero offset calibration)
7. Remove the brake plugs from the dummy limb
8. Move the joints and attach the dummy upper limb to the RACA robot using the orthoses

5.2.2 Environmental Conditions

The validation test should be performed under the use conditions set out by the RACA robot manufacturer.

5.2.3 System Conditions

The user of this protocol sets up the system conditions of the dummy upper limb as follows:

1. Set the rotational angle encoder resolution (1-10 bit)
2. Set the rotational angle encoder reading rate (1-5000 Hz)

5.3 Test Execution

The instructions for recording, logging, and pre-processing of the sensor data:

1. Start the RACA robot to execute the therapeutic motion exercise (Figure 15)
2. Stop the RACA robot
3. Detach the dummy upper limb from the RACA robot
4. Move the anatomical joints of the dummy upper limb to the calibration configuration: [0° 0° 0° 0° 0° 0° 0°]
5. Insert the brake plugs into the dummy limb
6. Export the measurement data from the PC test program in the form of a .csv file.

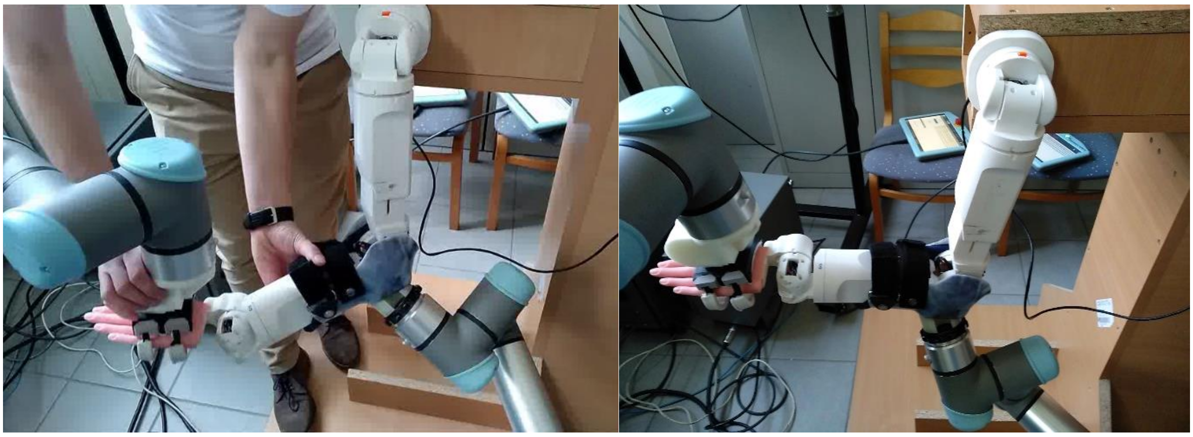


Figure 15: Safety assessment of a RACA robot. Left: the physiotherapist programs the RACA robot by hand guiding the dummy upper limb; Right: the RACA robot autonomously exercises the dummy upper limb

5.4 Data Analysis

To identify if hazard postures have occurred during a robotic rehabilitation session, the Data processing and Risk assessment software toolkit has to be used. The MS Excel toolkit consists of three working sheets (Sheet1, Sheet2, Sheet3) that can analyse and show both numerical and graphical results.

The instructions for data analysis:

1. Enter the upper and the lower limit start angles of the anatomical joint ROMs into the Sheet1 (Table 2)
2. Enter the percentage of the Take Care zone over the anatomical joint ROMs into the Sheet1 (Table 2)
3. Enter the individual upper limit and lower limit start angles of the anatomical joint overreaching risk Take Care zones into the Sheet1 (Table 3)
4. Copy the following measurement data from the exported .csv file into columns of the Sheet3 (Table 4):
    a. time (Column B)
    b. shoulder_exten\flex (Column D)
    c. shoulder_abdu\add (Column E)

   d. shoulder_inter\ext.rotation (Column F)
   e. elbow_ext\flex (Column G)
   f. wrist_sup\pron (Column H)
   g. wrist_rad\uln (Column I)
   h. wrist_flex\exten (Column J)
5. All other cells on all sheets of the Data processing and Risk assessment software toolkit are autofilled

Table 4: Sheet3 of the Data processing and Risk assessment software toolkit

frame	time		shoulder_exten\flex	shoulder_abdu\add	shoulder_inter\ext.rotation	elbow_ext\flex	wrist_sup\pron	wrist_rad\uln	wrist_flex\exten		shoulder_exten\flex	shoulder_abdu\add	shoulder_inter\ext.rotation	elbow_ext\flex	wrist_sup\pron	wrist_rad\uln	wrist_flex\exten
0	0.000		0	7.03125	11.601563	83.3203125	79.453125	5.2734375	1.0546875		0	7.03125	11.60156	83.32031	79.45313	5.273438	1.054688
1	0.033		0	7.03125	11.25	83.671875	79.453125	5.2734375	1.0546875		0	7.03125	11.25	83.67188	79.45313	5.273438	1.054688
2	0.067		0	7.03125	11.601563	83.671875	79.453125	5.2734375	1.0546875		0	7.03125	11.60156	83.67188	79.45313	5.273438	1.054688
3	0.100		0	7.03125	11.601563	83.671875	79.453125	5.2734375	1.0546875		0	7.03125	11.60156	83.67188	79.45313	5.273438	1.054688
4	0.133		0	7.03125	11.25	83.3203125	79.1015625	5.2734375	0.703125		0	7.03125	11.25	83.32031	79.10156	5.273438	0.703125
5	0.167		0	7.03125	11.25	83.671875	79.453125	5.2734375	1.0546875		0	7.03125	11.25	83.67188	79.45313	5.273438	1.054688
6	0.200		0	7.03125	11.25	83.671875	79.453125	4.921875	1.0546875		0	7.03125	11.25	83.67188	79.45313	4.921875	1.054688
7	0.233		0	7.03125	11.25	83.671875	79.453125	5.2734375	1.0546875		0	7.03125	11.25	83.67188	79.45313	5.273438	1.054688
8	0.267		0	7.03125	11.601563	83.671875	79.453125	4.921875	1.0546875		0	7.03125	11.60156	83.67188	79.45313	4.921875	1.054688
9	0.300		0	7.03125	11.25	83.671875	79.453125	5.2734375	1.0546875		0	7.03125	11.25	83.67188	79.45313	5.273438	1.054688
10	0.333		0	7.03125	11.25	83.3203125	79.453125	5.625	1.0546875		0	7.03125	11.25	83.32031	79.45313	5.625	1.054688

Suppose the user of this protocol intends to visually verify the risk postures in an ergonomics analysis and simulation tool equipped with Mocap (Motion Capture) data interface, then the data in Columns T-W (Table 5) can be transferred.

Table 5: Pre-processed data on Sheet3 for visual verification in an ergonomics analysis and simulation tool

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W
1	frame	time		shoulder_exten\flex	shoulder_abdu\add	shoulder_inter\ext.rotation	elbow_ext\flex	wrist_sup\pron	wrist_rad\uln	wrist_flex\exten		shoulder_exten\flex	shoulder_abdu\add	shoulder_inter\ext.rotation	elbow_ext\flex	wrist_sup\pron	wrist_rad\uln	wrist_flex\exten		time frame	wrist frame	elbow frame	shoulder frame
2	0	0,000		0	30,234375	1,054688	78,75	75,9375	4,21875	4,921875		0	30,2344	1,05469	78,75	75,9375	4,21875	4,92188		frame[0]=0;	frame[0]= (0,073631,0,085903,1,325359	frame[0]= (1,374447);	frame[0]= (0,018408,0,527689,0);
3	1	0,033		0	30,234375	1,054688	79,1015625	75,9375	4,21875	4,921875		0	30,2344	1,05469	79,1016	75,9375	4,21875	4,92188		frame[1]=0,0333;	frame[1]= (0,073631,0,085903,1,325359	frame[1]= (1,380583);	frame[1]= (0,018408,0,527689,0);
4	2	0,067		0	30,234375	1,054688	79,1015625	75,9375	4,21875	4,921875		0	30,2344	1,05469	79,1016	75,9375	4,21875	4,92188		frame[2]=0,0667;	frame[2]= (0,073631,0,085903,1,325359	frame[2]= (1,380583);	frame[2]= (0,018408,0,527689,0);
5	3	0,100		0	30,234375	1,054688	78,75	76,2890625	4,21875	4,921875		0	30,2344	1,05469	78,75	76,2891	4,21875	4,92188		frame[3]=0,1;	frame[3]= (0,073631,0,085903,1,331495	frame[3]= (1,374447);	frame[3]= (0,018408,0,527689,0);
6	4	0,133		0	30,234375	1,054688	79,1015625	75,9375	4,21875	4,921875		0	30,2344	1,05469	79,1016	75,9375	4,21875	4,92188		frame[4]=0,1333;	frame[4]= (0,073631,0,085903,1,325359	frame[4]= (1,380583);	frame[4]= (0,018408,0,527689,0);

5.5 Report

The safety test reports can be seen in numerical and graphical formats to determine whether the RACA robot passed or failed the test. Table 6 below shows a numerical format example of the test report. It reports the total time frames and the sampling frequency for that particular test in the first row. In rows 3-9, it reports the total number of frames in which the anatomical joint postures fall into the Prohibited zone (red), or into the Take Care zone (orange), or the Riskless zone (no colour). In rows 11-13, it reports the total number of frames in which the anatomical joint overreaching postures fall into the Prohibited zone (red), or into the Take Care zone (orange), or the Riskless zone (no colour).

The RACA robot has passed the test if the number of frames in which the anatomical joint postures fall into the Prohibited zone (red) is zero, and the anatomical joint overreaching postures fall into the Prohibited zone (red) is also zero. Quick visual check of the pass condition is provided if no red colour is present in the report.

Any non-zero frame numbers in the Prohibited zone mean no-pass test for the RACA robot.

Table 6: Numerical format of the ROB-LAJRM-LAJO-1 test report

total frames	2414	freq. [Hz]	30	
Joint	Movement	Number of risk postures for joint limit risk	Number of take care postures for joint limit risk	Number of frames without joints risk
wrist	Extension & Flexion	0	1	2413
	Radial & Ulnar Deviation	503	322	1589
	Pronation & Supination	1491	923	0
elbow	Flexion & Extension	1	0	2413
shoulder	Adduction & Abduction	0	0	2414
	Flexion & Extension	0	0	2414
	Exernal & Internal rotaion	0	0	2414
Number of overreaching postures		1		
Number of overreaching take care postures		0		
Number of frames without overreaching risk		2413		

On Sheet3 it is possible to navigate to each time frame featuring a risk (Table 7).

Table 7: Frame by frame report of the ROB-LAJRM-LAJO-1 test

frame	time	wrist Extension & Flexion	wrist Radial & Ulnar Deviation	wrist Pronation & Supination	elbow Flexion & Extension	shoulder Adduction & Abduction	shoulder Flexion & Extension	shoulder Exernal & Internal rotaion	Overeaching detection
460	15.33333333	-34.453125	12.3046875	79.8046875	84.375	4.921875	0	-6.6796875	Not overreaching
461	15.36666667	-34.453125	11.953125	79.453125	84.7265625	4.921875	0	-6.6796875	Not overreaching
462	15.4	-34.8046875	12.3046875	79.453125	84.375	4.921875	0	-6.6796875	Not overreaching
463	15.43333333	0	0	79.453125	0	4.921875	0	-6.6796875	Overreaching!
464	15.46666667	-35.15625	11.953125	79.8046875	84.375	4.5703125	0	-6.6796875	Not overreaching
465	15.5	-35.15625	11.953125	79.8046875	84.7265625	4.921875	0	-6.6796875	Not overreaching
466	15.53333333	-35.5078125	11.953125	79.8046875	84.7265625	4.921875	0	-6.6796875	Not overreaching
467	15.56666667	-35.859375	11.953125	79.8046875	84.7265625	4.921875	0	-7.03125	Not overreaching
468	15.6	-35.859375	11.953125	79.8046875	84.375	4.921875	0	-6.6796875	Not overreaching
469	15.63333333	-35.859375	11.953125	79.8046875	84.375	4.921875	0	-7.03125	Not overreaching
470	15.66666667	-76	11.953125	80.15625	84.375	4.921875	0	-6.6796875	Not overreaching
471	15.7	-36.2109375	11.953125	79.8046875	84.375	4.921875	0	-6.6796875	Not overreaching
472	15.73333333	-36.5625	11.953125	79.8046875	84.7265625	4.5703125	0	-6.6796875	Not overreaching
473	15.76666667	-36.5625	11.6015625	80.15625	84.7265625	4.921875	0	-6.6796875	Not overreaching
474	15.8	-36.9140625	11.6015625	80.15625	84.7265625	4.5703125	0	-6.6796875	Not overreaching

Figure 16 below shows a graphical format example of the test report. Seven pie charts illustrate the anatomical joint ROM risks and one pie chart illustrates the anatomical joint overreaching risk. The rates of anatomical joints movement duration in the Prohibited, in the Take care, and in the Riskless zones over the entire therapeutic movement duration are overprinted on the pie charts in %.

The RACA robot has passed the test if all the eight rates related to the Prohibited zones are equal to 0%. Quick visual check of the pass condition is provided if no red colour is present in any pie chart.

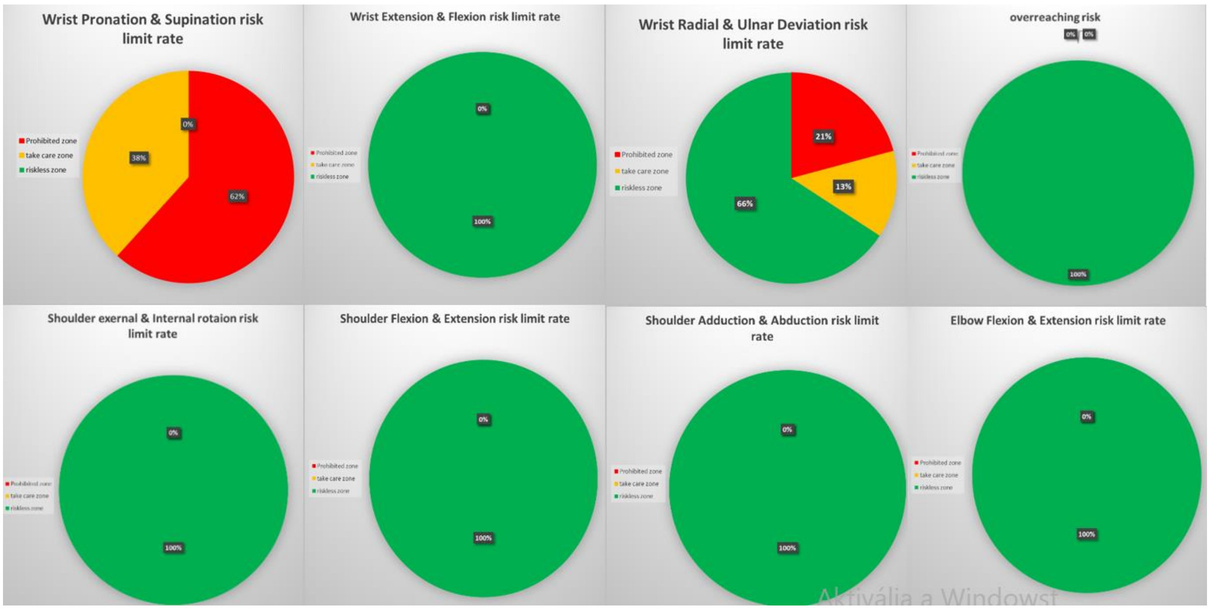


Figure 16: Graphical format of the ROB-LAJRM-LAJO-1 test report

6 Annexes

6.1 Report form

Test form - Protocol ROB-LAJRM-LAJO-1	
Test date:	
Tester's name:	
RACA robot:	
Safety Skill#1:	limit anatomical joint range of movement
Safety skill#2:	limit anatomical joint overreaching
Measurement system:	Sensorized dummy upper limb and Data processing and Risk assessment software toolkit
Length of the upper arm [mm]:	
Length of the lower arm [mm]:	
Anatomic size for Male/Female [M/F]:	
Height of the shoulder enclosure [%]:	
Side [Left/Right]:	
Rotational angle encoder resolution [bit]:	
Rotational angle encoder reading rate [Hz]:	
Name of the .csv file:	
Wrist extension and flexion ROM upper limit start angle [degree]	
Wrist extension and flexion ROM lower limit start angle [degree]	
Wrist radial and ulnar deviation ROM upper limit start angle [degree]	
Wrist radial and ulnar deviation ROM lower limit start angle [degree]	
Wrist pronation and supination ROM upper limit start angle [degree]	
Wrist pronation and supination ROM lower limit start angle [degree]	
Elbow flexion and extension ROM upper limit start angle [degree]	
Elbow flexion and extension ROM lower limit start angle [degree]	
Shoulder adduction and abduction ROM upper limit start angle [degree]	
Shoulder adduction and abduction ROM lower limit start angle [degree]	
Shoulder flexion and extension ROM upper limit start angle [degree]	
Shoulder flexion and extension ROM lower limit start angle [degree]	
Shoulder external and internal rotation ROM upper limit start angle [degree]	

Shoulder external and internal rotation ROM lower limit start angle [degree]	
Percentage of the Take Care zone over the anatomical joint ROMs [%]	
Wrist extension and flexion overreaching upper limit start angle [degree]	
Wrist extension and flexion overreaching lower limit start angle [degree]	
Wrist radial and ulnar deviation overreaching upper limit start angle [degree]	
Wrist radial and ulnar deviation overreaching lower limit start angle [degree]	
Elbow flexion and extension overreaching upper limit start angle [degree]	
Elbow flexion and extension overreaching lower limit start angle [degree]	
Name of the Data processing and Risk assessment .xlsx file:	
Total number of frames in the test exercise:	
Duration of the test exercise= number of frames/reading rate [sec]	
Safety Skill#1 pass [Y/N]	
If no-pass for Safety skill#1, the rate of anatomical joints movement duration in the Prohibited zone over the entire therapeutic movement duration [%]	
Safety skill#2 pass [Y/N]	
If no-pass for Safety skill#2, the rate of prohibited anatomical joints overreaching movement duration over the entire therapeutic movement duration [%]	
Overall conclusion:	
Signature:	

6.2 The effect of the simplified shoulder biomechanical model on the safety assessment

The shoulder complex of the dummy upper limb is limited to a 3 DOF ball joint mechanism, whereas the accurate model of the shoulder complex has 5 DOFs. How does this limitation affect the reliability of the Safety Skill #1: limit anatomical joint range of movement and the Safety Skill #2: limit anatomical joint overreaching?

The scapulohumeral rhythm is activated after 30 degrees of shoulder abduction with ratio of 1:2 scapula to humeral (Figure 17). Therefore the centre of rotation of the upper arm is shifted vertically when larger abduction angle is reached. To illustrate this effect a red arrow represents the dummy upper limb, and a blue arrow represents the hypothetical real upper limb in Figure 17. We can state that the 3 DOF shoulder of the dummy limb conservatively affects the reliability of the Safety Skill #1: limit anatomical joint range because the real shoulder abduction angle is equal (in the range of 0-30 degrees) with or proportionally higher (in the range of 30-180 degree) than the real shoulder abduction angle. A RACA robot passed the Safety Skill #1: limit anatomical joint range test with the dummy upper limb, including a 3 DOF shoulder joint is always safe for real upper limb therapy.

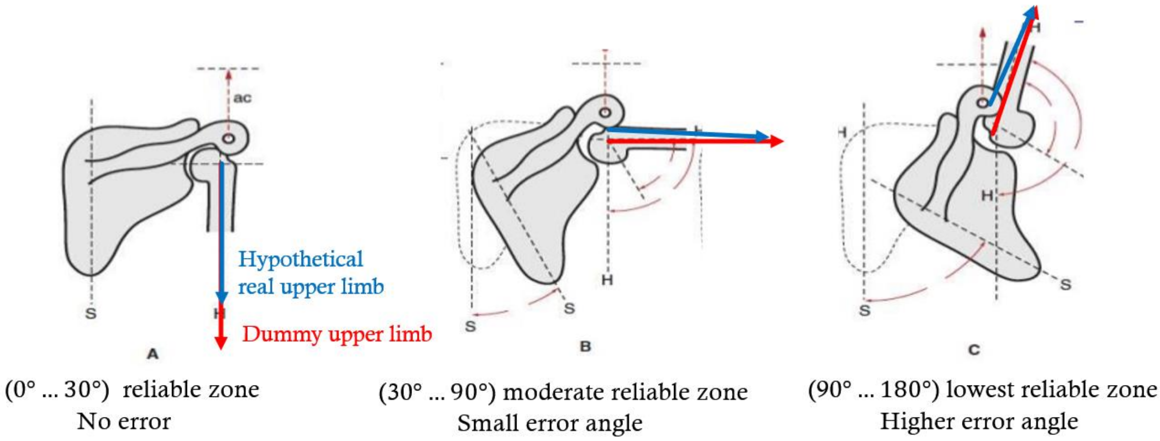


Figure 17: Safety Skill reliability zones depend conservatively on the scapulohumeral rhythm

Concerning the effect of the scapulohumeral rhythm on the Safety Skill #2: limit anatomical joint overreaching, no strict dependence can be justified. Since the position error of the shoulder rotation centre may positively and negatively affect the elbow and wrist anatomic joint angles, only the proper range of the anatomical joint overreaching Take Care zones can ensure the reliability of the RACA robot test for the Safety Skill #2: limit anatomical joint overreaching

6.3 Potential further development

The artificial dummy upper limb equipped with seven rotational angle encoders in the shoulder, elbow, wrist joints, and the Data processing and Risk assessment software toolkit used in this protocol have a potential for further development:

- All measurement data are at hand in the Data processing and Risk assessment software toolkit to assess anatomic joint angular speed (overspeeding) risk.
- The Data processing and Risk assessment software toolkit could enable online real-time safety assessment of a RACA robot. This way the user of the protocol could test the operation of the safety devices of the RACA robot.
- Using open-source software, a mannequin-based graphical motion visualization module could be integrated with the Data processing and Risk assessment software toolkit.
- The dummy upper limb could assess excessive anatomical joint force (over forcing) risk if brakes and force/torque sensors were built in it.
- The shoulder joint can be extended from a 3 DOF version to a 5 DOF version.