Being safe around collaborative and versatile robots in shared spaces

Protocol

Test Limit Restraining Energy for Upper Limb Exoskeleton Type RACA Robots

(EXO-LRE-2)

This protocol is to be used to test the restraining energy that can be applied to a human subject during use of an exoskeleton used for upper limb support. This protocol is both aimed at exoskeletons used in the medical domain as well as at exoskeletons used in the industrial, logistic or agricultural domain.

Readiness Level	Description
6	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!

DANISH TECHNOLOGICAL INSTITUTE
Fraunhofer IFF
cea
National Research Council of Italy
Roessingh Research and Development

Grant agreement no. 779966
Date December 8, 2021

CONTENTS

1 Introduction

In a restrain type robot, like exoskeletons, exoskeleton type gait trainer robots etc., a human is in continuous contact with the robot via a restraining connection, e.g. via straps, cuffs etc. This restraining connection is required to facilitate a controlled exchange of energy between the robot and the human subject to achieve the primary functionality of the robot. During this exchange of forces, due to multiple causes, undesired forces may be applied to the attached human subject.

The purpose of this protocol is therefore to validate the safety skill to limit undesired energy exchange between a restraint type robot and a human subject using an instrumented limb.

This protocol is based on results from the COVR FSTP project “ExoSafe” which was executed by the Spanish National Research Council (CSIC) in Spain, the Vrije Universiteit Brussel (VUB) in Belgium and the Jozef Stefan Institute (JSI) in Slovenia.

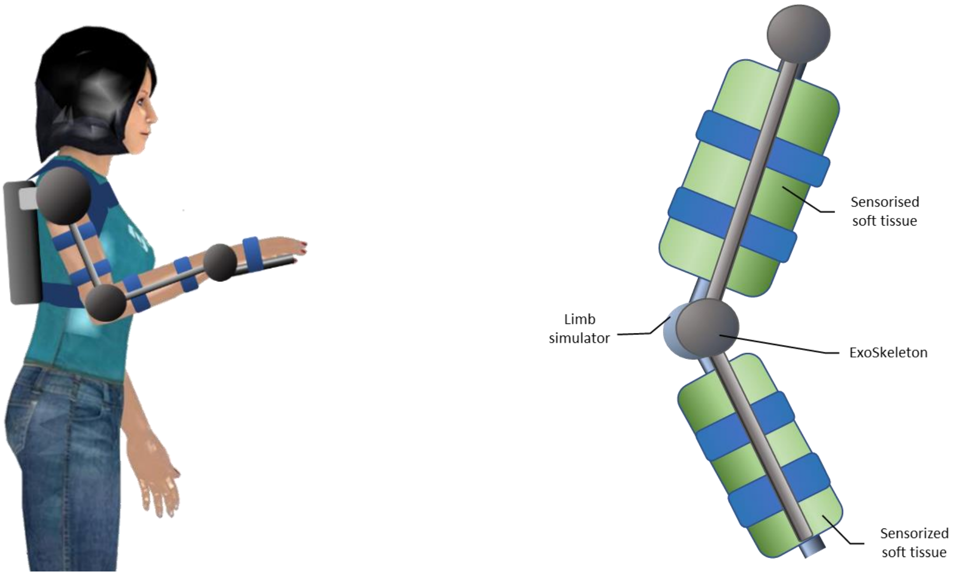

Figure 1: Exemplary application featuring situation

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	Limit Restraining Energy
System	Upper limb Exoskeleton, Restrain type RACA robot*
Domain	Healthcare, Industry, Logistics
Conditions	Indoor
Measurement Device(s)	(Passive) Instrumented limb

⚠	**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

Exoskeleton (SOURCE: ASTM F3332-20)

Wearable device that augments, enables, assists, and/or enhances physical activity through mechanical interaction with the body.

Exoskeleton system (SOURCE: ASTM F3323-20)

Exoskeleton and all associated components, equipment, software, and communications necessary to make it fully functional

Instrumented limb (source: local to this document)

Measurement device, shaped in the form of a human limb and which can move like a passive or active human limb, consisting of at least one hinge type joint and a force/torque sensor. For safety testing purposes this device can replace a human limb.

Mirror limb (source: local to this document)

A non-instrumented version of the instrumented limb, for testing purposes where 2 limbs are required for the intended use of the RACA robot

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: EN-IEC 80601-2-78:2020 – clause 201.3.212)

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

Rehabilitation robot

RACA robot used in rehabilitation.

S.F.C./Single fault condition (source: EN-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.

2 Concept and Objectives

2.1 Hazardous Situations

A hazardous situation can occur when in an restrain type RACA robot* forces are applied to (parts of) the human limb. For the intended use of this kind of RACA robot* transfer of forces usually is required to achieve the intended effect. The magnitude of force transmission is directly related to safety. However, little literature is available concerning force limits based on experiments with humans.

When forces are applied over a long time period, they may lead to skin or tissue damage (e.g. blisters or bruises) or, in more extreme cases, even damaged ligaments or bone fractures. Unintended forces may also be caused by a misfit of the restraint type RACA robot* to the human anatomy. This may result in a non-optimal transfer of the required force, leading to additional forces acting in unintended directions (e.g. shear forces) on the human.

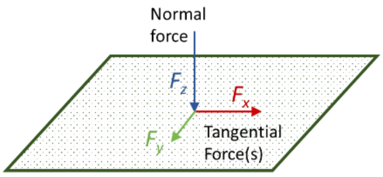

Figure 2 Force components

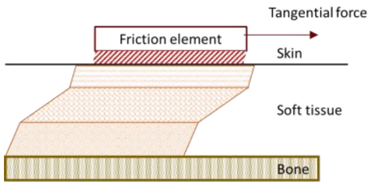

Figure 3 stress effect tangential force

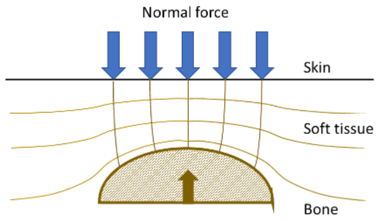

Figure 4 stress effect normal force[1]

Another reason for the localized appearance of excessive forces may be due to the shape of the human body part and the restraining adaptor (cuff/strap etc.) used for the interface. A misfit of a cuff may lead to a very localized point of application of the force on the human body, which may lead to local pressure points, blisters etc.

Since many of the users of these exoskeleton type RACA robots* have impaired sensitivity in their limbs, early detection of such undesired side effect by the user can be a problem and therefore cannot be relied upon.

2.2 Target Behavior and Metrics of the Safety Skill

To avoid the hazards mentioned in the previous paragraph, risk reduction measures, like self-alignment or compliance in the physical robot-human interface, may have been implemented in the exoskeleton design to avoid or reduce the risk of the hazard occurring.

The target behavior of the safety skill to be validated is to limit the application of undesired forces, while maintaining the intended behavior of the RACA robot*.

For that we need to make a distinction between desired and undesired forces.

Normal force $\boldsymbol{F_z}$ [N]: Force perpendicular to the leg shell.
Responsible for compression, deformation, and distortion of the underlying soft tissues and produces shear within and between tissue layers

Tangential forces $\boldsymbol{F_x}, \boldsymbol{F_y}$ [N]: Forces tangential to the leg shell.
Responsible for displacements and deformation of the deeper tissues, and blood vessels compression and distortion.

It is assumed that the normal forces are used to create the intended action of the RACA robot*, but may result in some undesired effects in underlying tissues. Tangential forces are usually undesired and may be due to a misfit of the RACA robot* with the human anatomy.

The behavior of the safety skill, i.e. limit restraining energy, can be validated by continuously measuring the interaction forces between the RACA robot* and a physical representation of a human (e.g. an instrumented limb*) during normal behavior of the RACA robot*.

Relative movements between the locations and orientations of the axes of rotation of both the joint of the exoskeleton and the joint of the Instrumented Limb* can be measured.

[1] Images from deliverable D2.1 from the COVR FSTP project Exosafe

Since perfect alignment during movements may not be achieved, additional forces and torques inside the instrumented limb*, as well as at the contact areas between the RACA robot* and the instrumented limb* will be measured to detect possible excessive values during these movements.

The measured forces and torques, combined with the relative displacements, will provide information about the effectiveness of the safety skill "limit restraining energy".

For validating this robot safety skill, the output targets are:

- **Maximum absolute peak force, F_{absM} [N]**: maximum value of the absolute value a force component reaches during the test. This measure is related to instant pain detection
- **Average force, F_{av} [N]**: mean value of the force component during the performed test. This SI is related to time distributed pain [11]

The values for the target metric should be determined during the risk assessment. For this validation protocol, the target metrics are [… (e.g., extremal values like maximum force)] of the mentioned output quantities:

- Target metrics (e.g., maximum force or peak pressure), value = [insert from risk assessment]

At the time of writing of this protocol no well-established limit values are known.

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

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 Annex A.

3.1 System

The system under test consists of a restrain type RACA robot*. The outcomes of the tests, i.e. the measured forces and pressures, may vary according to the maximum amount of flexion applied to joints as well as the velocity at which the flexion and extension movements are applied. At the least, tests should be performed under maximum velocity and flexion angle. Weights of the involved segments may also influence the outcome of the tests. Therefore, the tests should be performed for segment masses that are representative for the specified max weight of the subject.

When the limb of the subject may influence the safety skill of the RACA robot*, by activity of the human limb, the tests should also be performed using an active instrumented limb* that is able to mimic the expected activity of a user. This activity should then be set to mimic a worst-case situation.

The tests should therefore be performed:

- Under the specified maximum normal use speed v [m/sec]
- Reaching the specified maximum flexion angle α [deg] during normal use.

- Under the specified load conditions that are representative for normal use.
- With an active RACA robot* and a completely passive instrumented limb*
- When relevant, also with an active RACA robot* and a (partially) active instrumented limb*[2]

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

The parameters mentioned above and instrumented limb* settings used during the tests should be recorded in the test form in Annex A.

When relevant, mounting or placement of the RACA robot* for the tests should be in such a manner that it represents as close as possible a normal used situation. When fixation to proximal body parts is required in normal use situations, suitable representations of these body parts should be part of the test setup

3.2 Environment

Environmental conditions may have a significant effect on outcomes of the tests. When the intended use and the risk assessment identify certain conditions that may influence the safety skill, these conditions should be incorporated in the tests.

Conditions that may influence the safety skill might be:

- Orientation of the subject during normal use of the setup (e.g. seated, standing, lying)

3.3 Miscellaneous

N.A.

4 Setup

4.1 Equipment

An instrumented limb* is used to mimic a human limb during normal use of the exoskeleton. The instrumented limb* is equipped with multiple force sensors, that measure the net total of forces applied to specific areas of the instrumented limb* in 3D. These areas are defined by the attachments where the restrain type RACA robot* interacts with the subject. In those areas either the instrumented limb* can also be equipped with pressure sensors or additional pressure sensors can be added, to measure the pressure distribution between the restrain type RACA robot* and the instrumented limb*. This instrumented limb* preferably also should measure the joint angles during movements, to provide information about the timing of the potentially hazardous situation.

The instrumented limb* consists of:

- at least a single joint that mimics the behavior of the corresponding human joint – but preferably mimics the entire limb.
- force sensors to measure the 3D net forces in separate interaction areas on the limb.
- sensors to measure the angle between the segments
- segments that mimic the shape of a human limb

[2] This protocol does not cover the use of a (partially) active instrumented limb*

- A cover material that mimics the properties of human skin and underlying soft tissues as described in annex B of ISO TR 23482-1:2020

To gain a more detailed insight into the force distribution in these interaction areas, optionally pressure sensor arrays can be used to map the local force distribution.

Preferably the instrumented limb* is attached to a dummy torso via a joint that at least mimics the passive behavior of the shoulder joint, so the upper limb exoskeleton can be attached to the “body” as would be in a normal use case.

The weight of the instrumented limb* should match that of the intended use population. According to IEC 60601-1 for adults the total body weight is set at 135 kg plus 15 kg for accessories. When the system is intended to be used by children a lower weight can be used. The segment mass for the upper arm, the lower arm and the hand as a percentage of the total body mass can be found in Table 1.

Table 1: Body segment parameters[3]

Segment mass (Percentage of body mass)		
Segment	**Males**	**Females**
Upper arm	3.25	2.90
Forearm	1.87	1.57
Hand	0.65	0.5

Details about the used sensing devices must be recorded in the test report (Annex 0)

4.2 Method

The instrumented limb*, used to measure interaction forces with the RACA robot*, is mounted to a mannequin torso via a passive joint that represents the shoulder. For simplicity the shoulder can be represented by a 3 DOF ball joint. If required a more realistic 5 DOF representation of the shoulder should be used.

The whole setup consists of a mannequin torso and instrumented limb*. The mannequin torso is firmly fixated in space, in a location where the required movements of the limb can be freely executed, and oriented as required for the normal use situation.

[3] From Plagenhoef et al, 1983

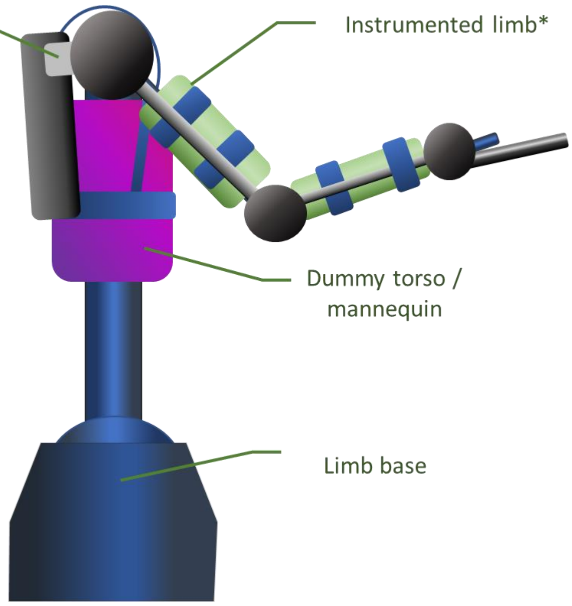

Figure 5: General structure of an appropriate test arrangement with the exoskeleton fitted to an instrumented limb (incl. base and dummy torso)*

The instrumented limb* is connected to the mannequin trunk via an artificial joint, that mimics the shoulder joint.

The exoskeleton will be attached to the instrumented limb* and, when required for normal use situation, to the mannequin.

The exoskeleton will use its own control hard- and software, which is set-up with normal use settings.

4.2.1 Data Acquisition

Data acquisition should be done using suitable acquisition rates. Since tests will be performed under normal motion speeds, acquisition rates of at least 50 Hz should be used for all used measurement systems. To allow for signal conditioning on the sensor data from the instrumented limb* an acquisition rate of at least 200 Hz is advised.

Synchronization between the instrumented limb* and the optional pressure sensing system is preferred, but not mandatory.

Synchronization between the instrumented limb* and RACA robot* is preferred, but not mandatory.

5 Procedure

5.1 Test Plan

The test plan is a summary of all situations, which the risk assessment identified as hazardous due to the continuous interaction between the RACA robot* and the subject, incl. all combinations of applicable conditions. Therefore, the test plan provides a detailed summary which tests are necessary to validate the skill for the considered application.

All combinations of the conditions, introduced in section 3 that are applicable and may change in the considered situation, result in a list of concrete test cases. The protocol must consider the following conditions:

- Robot system
  - the instrumented limb* should have segment weights that correspond with the max weight allowed for the exoskeleton, as defined by the manufacturer. The weight should be recorded in the test form (Annex 0).
  - The movement pattern/trajectory needs to be defined.
- Sub-system
  - The mannequin torso should be anatomically shaped, to facilitate correct normal used attachment of the exoskeleton/RACA robot* (if required)
  - The mannequin torso should be positioned firmly
  - The mannequin torso should be oriented similar to normal use situations
- Environment
  - All environmental conditions that may influence the effectiveness of the implemented safety skill must be considered
- Miscellaneous
  - N.A.

We recommend preparing this list before beginning the tests. Please apply Sections 5.2 to 5.5 for each test case and run each test at least three times.

5.2 Preparation

Before executing a particular test from the test plan, it is necessary to prepare the setup and the conditions properly. The following sections 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

- Define the motion pattern/trajectories used during the tests and note these in the test form (Annex 0)
- Position the mannequin torso
- Fix the instrumented limb* to the mannequin torso
- The exoskeleton is fixed to the mannequin torso and the instrumented limb* following the guidelines of the exoskeleton manufacturer
- Check connections and signals for the instrumented limb*
- Connections for communication, and optional trigger are connected to the exoskeleton.
- The battery of the exoskeleton is connected.
- The power supply and communication connection are connected to the instrumented limb*.

5.2.2 System Conditions

- The system should be tested under the main relevant orientations that may have an impact on the implemented safety skill.
- If needed, a soft tissue material, as specified in ISO TR 23485-2:2020, should be placed under each cuff. The use of a soft tissue simulating material should be noted in the test form
- The tests should be executed under normal use conditions as well as for those SFC's* that may have an impact on the implemented safety skill. The test condition should be noted in the test form (Annex 0).
- The tests should at least be performed using motion patterns/trajectories that mimic normal use situations where worst case situations may be expected.

5.2.3 Environmental Conditions

List the relevant environmental conditions under which the tests should be performed.

The used environmental condition during the test should be recorded in the test form (Annex 0)

5.3 Test Execution

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

- The exoskeleton straps are adjusted on the instrumented limb* the preferred configuration of cuff position and tightening level
- The exoskeleton is controlled to reach its initial position (all the limbs aligned with the exoskeleton in standing position)
- Data acquisition is started for the instrumented limb*.
- The program controlling the exoskeleton is launched.
- The exoskeleton is started to generate the predefined motion pattern.
- The previously defined motion pattern is kept running for at least 3 minutes.
- The exoskeleton stops the motion pattern after the desired time.
- Data acquisition is stopped for the instrumented limb*.

5.4 Data Analysis

Data from the sensors in the instrumented limb* may be filtered using a second order, zero phase low pass Butterworth filter, with a cut off frequency of 25 Hz.

The values need to be compared with values defined in the risk assessment to determine whether the residual risk is acceptable, since no generally established limit values for a pass / no pass criterion are known yet.

5.5 Report

Use the form in Annex A to report all conditions and results of the tests. After finishing the validation successfully (all tests passed), add the forms to your risk assessment. They are proof that the applied safety skill is active and gives the expected protection to the robot operator working beside the collaborative robot.

Use the last section (summary) in the form to record the overall result of the test (passed/failed).

COVER
safearoundrobots.com

6 Bibliography

EN-IEC 60601-1:2006

EN-IEC 80601-2-78:2020

Clauser, C. E., McConville, J. T., & Young, J. W. Weight, volume, and center of mass of segments of the human body. WADC Technical Report, AMRL-TR-69-70, Wright-Patterson Air Force Base, Dayton, OH,1969

Dempster, W. T. Space Requirements of the Seated Operator. WADC Technical Report, 55-159, WrightPatterson Air Force Base, Dayton, OH, 1955.

Plagenhoef, Stanley & Evans, F. & Abdelnour, Thomas. (1983). Anatomical Data for Analyzing Human Motion. Research Quarterly for Exercise and Sport. 54. 169-178. 10.1080/02701367.1983.10605290.

Annex A - Test form

Limit restraining energy for upper extremity exoskeleton

Test form - Protocol EXO-LRE-2			
Test date		**Name of tester:**	
Test ID		**Hazard ID**	
Picture of test setup			
System and System conditions			
Description of RACA robot* under validation			
Type RACA robot*		**SN**	
Motion pattern used (reference or description)			
	Height	**Anterior/posterior**	
Initial misalignment shoulder instrumented limb			
Load used			
Velocity			
Control mode RACA robot*	Full control / Co-control		
Connection areas:	**Location**	**Limit max force**	**Limit average force**
A[4]			
B			
C			
D			
E			
F			
G			
H			
…			
Picture of test setup with-numbering of connection areas			

[4] Example areas – e.g. *Upper arm front upper attachment* – number and description of area locations can be modified as needed

Conditions: Enviromental	
Orientation of user:	Standing / Sitting / Lying

Conditions: Miscellaneous	

Target Metrics	
Max normal force Fz	N
Max tangential force Fx	N
Max tangential force Fy	N

Measurement system			
Measurement system used:			
Calibration date:		**Measurement accuracy:**	
Instrumented limb used:			
Calibration date:		**Acquisition rate (Hz)**	
Limb active during test?			
Limb movement pattern description / file			

Test results

Connection area	Maximal force (N)	Average force (N)		Pass/no pass
A				
B				
…				

Summary EXO-LRE-2 tests

Date of testing	
Name of tester	
Overall conclusion	
Signature	