Being safe around collaborative and versatile robots in shared spaces

Protocol

Test exoskeleton for maintaining proper alignment for hinge type joints

EXO-MPA-1

This protocol describes a method for validating the safety skill "Maintain proper alignment" for joint axis alignment (both translational as well as rotational) for exoskeleton type rehabilitation robots as well as exoskeleton type robots used in other domains. This protocol uses an instrumented artificial limb, by which the joint angles, contact forces as well as the forces and torques in the joint can be determined, to validate the skill.

Readiness Level	Description
7	Protocol in 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!

Grant agreement no. 779966
Date August 24, 2021

CONTENTS

1 Introduction

In exoskeleton type robots, alignment of the effective exoskeleton joint relative to the human joint can be a challenge. Inaccurate fitting of an exoskeleton can cause serious adverse misalignment effects, but even in carefully adjusted exoskeletons, donning and doffing may cause similar effects. These joint misalignments can appear in various forms:

- A shift or offset of the exoskeleton flexion axis relative to the flexion axis of the human joint, where both axes remain parallel. (Figure 1 A)
- A rotation of the exoskeleton flexion axis relative to the flexion axis of the human joint, around an axis perpendicular to the flexion axis of the human joint, so the axes don't stay parallel.(Figure 1 B)

These kinds of misalignments may result in reddening of the skin, or skin damage in those places where the robot is attached to the human, as well as bruises or in very serious cases even bone fractures.

Many developers and manufacturers have recognized these joint misalignment problems and have come up with various strategies to avoid or compensate for these possible misalignments.

The purpose of this protocol is therefore to validate the implementation of the safety skill to *maintain proper alignment* for joints in exoskeleton type robots relative to the joint of the user, thus avoiding adverse effects of misalignments for the user.

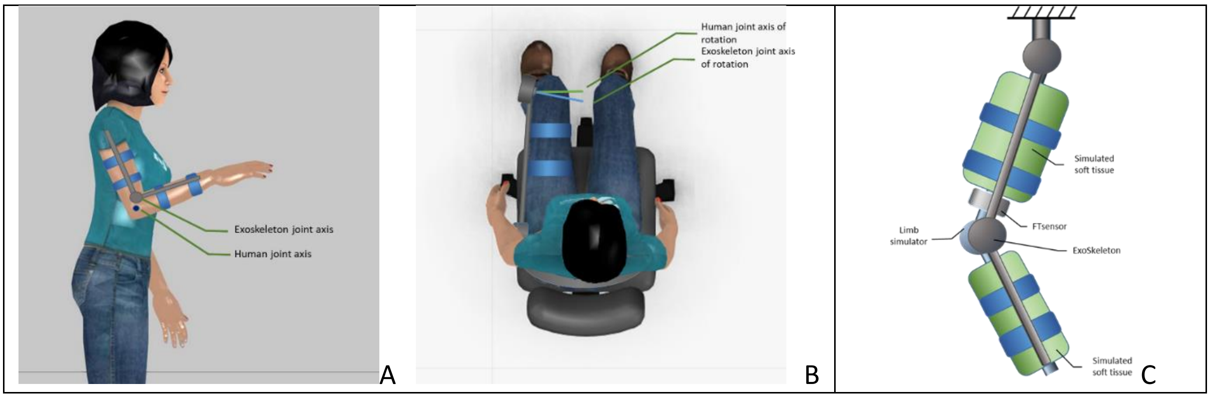

Figure 1: Example images for translational (A) and rotational (B) exoskeleton misalignment – and validation setup (C)

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	Avoid joint misalignment - reduce the effect of translational joint misalignment of a hinge type joint of a human limb and a robot joint
System	Exoskeleton or restrain type RACA robots with multisegment attachment and hinge type joints[1]
Domain	Healthcare or personal care robots in other domains
Conditions	• distal segment of the joint is not in contact with non-movable object • distal segment is in contact with non-movable object
Measurement Devices	Instrumented artificial limb and Opto electronic motion capture system (or equivalent)

[1] In this protocol the term exoskeleton may be used for both exoskeletons and restrain type RACA robots

	Warning
⚠	This protocol supports users to validate the effectiveness of the skill listed in the profile above. The skill should be a technical measure of the system integrator applied to mitigate the risk of one potentially hazardous situation as identified in the risk assessment which the reader has to be done before using this protocol. In general, the risk assessment is a mandatory and helpful source to identify test situations and conditions relevant for a proper validation.

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

Instrumented limb (source: local to this document)

Measurement device, shaped in the form of a human limb and which can move like a passive human limb, consisting of at least 1 hinge type joint and a force/torque sensor. For safety testing purposes this device can replace a human limb.

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 the exoskeleton segments of the robot are not exactly positioned in a predefined position at the subjects' limb segment or move from that position during use. This can be caused by an incorrect/inaccurate fitting of the exoskeleton to the specific anatomy of a patient, who will be wearing the exoskeleton type RACA robot*. Such inaccuracies may lead to a misalignment of the human joints and the joints of the robot due to a translational shift of the robot rotation axis relative to the axis of rotation of the human joint.

Also, the exoskeleton joint may not perfectly mimic the movements of the human joint, which also can lead to unintended additional forces and torques or an unintended shift of the body part relative to the exoskeleton.

Additionally, while using an exoskeleton type RACA robot*, which in itself may be properly fitted to the patient, donning of the exoskeleton by the patient, possibly unsupervised, may lead to a misalignment of the axes of rotations. Often this can be a misalignment in the form of a misalignment of the rotation axes in the transverse plane.

These misalignments may result in the hazardous situation where the flexion axis in the joint of the robot is not exactly aligned with the flexion axis in the subjects' limb joint. This may result in unintended forces and torques at the contact points between the subject and the exoskeleton type robot as well as unintended forces and torques in the subjects' joint. When these unintended forces and torques exceed critical levels, they may lead to skin or tissue damage (e.g. blisters or bruises) or, in more extreme cases, even to damaged ligaments or even bone fractures.

Since many of the users of these exoskeleton type RACA robots* have impaired sensitivity in their limbs, early detection of misalignment 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, measures, like self-alignment, may have been implemented in the exoskeleton design to avoid or reduce the risk of the hazard happening.

The behavior of the safety skill, i.e. maintain proper alignment, can be validated by measuring the location and orientation of the joint of the exoskeleton as well as the location and orientation of the subjects' joint during movements.

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.

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 exoskeleton 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 "maintain proper alignment"

For validating this robot skill the output targets are:

- Force: continuous measurement of internal 3D force in the subject joint [N], combined with the joint angle
- Torque: continuous measurement of internal 3D torque in the subject joint [Nm], combined with the joint angle

To verify the amount of misalignment applied the offset between the flexion axis of the instrumented limb and the exoskeleton joint should be measured.

The values for the target metric should be determined during the risk assessment. For this validation protocol, the target metrics are:

- Force and torque values in the joint[2]. Limit values have to be defined by the manufacturer.

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

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 A.

3.1 System

The system under test consists of an exoskeleton type RACA robot*, for which tests are applied to a single joint. The outcomes of the tests, i.e. the measured forces and torques, can increase by the amount of flexion applied to the joint as well as the velocity at which the flexion and extension movements are applied. So at least tests should be performed under maximum velocity and flexion angle. Also loads applied to the joint (either during a load taking phase or a during free swinging motion) may influence the forces and torques in the joint. These conditions should also be considered. Here also special attention may need to be given to a possible variating load profile during normal use situations.

The tests should therefore be performed:

- Under maximum normal use speed v [deg/s].
- Using maximum flexion angle α [deg] during normal use.
- Under (well described) load conditions that are representative for normal use. (F_{3x1} [N], including force vector orientation)
- Up to the translational misalignment d [mm] (which can be both a anterior/posterior translation or a vertical translation) for which the misalignment compensation was specified for.
- Up to the misalignment angle β [deg] in the transverse plane for which the misalignment compensation was specified for.

Apply this protocol for the complete system as is normally used. Perform the tests both under normal use conditions as well as relevant S.F.C.* which may influence the safety skill.

The above mentioned parameters used during the test should be recorded in the test form.

3.2 Sub-System

Fixation of the more proximal segments (e.g. the pelvic segment) of the exoskeleton to the "proximal" part of the instrumented limb* may have significant effects on the outcomes of the test. Therefore the attachment method during the validation tests has to be described clearly.

Compliance in the connections between the exoskeleton and the human limb, i.e. cuffs and straps, will have a significant effect on the outcomes of the test. Therefor these tests need to be performed with the cuffs and straps used. If also other cuffs and/or straps are used, tests have to be performed with these other options as well.

[2] From literature currently there are no proper reference values known, however this may change based on research in this field

The method of attachment of a distal segment (e.g. a foot) may also have a significant effect on the outcome of the tests and has to be considered as well.

3.3 Environment

No specific environmental conditions are expected that could influence the safety skill.

4 Test setup

4.1 Sensing devices

An instrumented instrumented limb* is used during the tests, to measure forces and torques that may appear inside a limb and forces that may externally act on a limb. The instrumented limb* preferably also should measure the joint angle during movements in order to provide a reliable force-torques/angle relation. The instrumented limb* should be mounted in the exoskeleton.

This device consists of:

- at least a single joint that mimics the behavior of the corresponding human joint.
- 1x 6-DoF Force/Torque sensor mounted in the simulated limb (as part of the "skeleton")
- 1 angle sensor to measure the angle between the 2 segments
- A cover material that mimics the properties of human skin and underlying soft tissues as described in annex B of ISO 23482-1:2020

Since accurately misaligning the instrumented limb* relative to the exoskeleton can be a challenge, the amount of misalignment during each test should be measured as well. This can be done using an opto-electronic motion capture system. Optical retro-reflective markers need to be placed either on locations from which the position and orientation of the joint axes of the instrumented limb and the exoskeleton can be derived, e.g. by placing them in line with the flexion axes. Placing additional markers on the segments of the exoskeleton and the instrumented limb*, so that per segment at least 3 non-linear markers are placed, could add information so the 3D movements of each of the segments can be determined. This provides additional synchronized information about the movements of both the instrumented limb and the exoskeleton, so the displacements of the instrumented limb* relative to the exoskeleton during movements can be measured. These displacement values derived from this marker data can be used to validate whether the displacements of the limb vs. the exoskeleton remain within the limits specified by the manufacturer. If this information can be obtained in any other way, the motion capture system might be omitted during these tests.

4.2 Method

The instrumented limb* is fitted into the exoskeleton (see Figure 2). Tests will be performed with the limb flexion axis aligned with the exoskeleton according to the fitting instructions of the manufacturer.

An opto-electronic motion capture system will be used to track the motions of both the instrumented limb* and the exoskeleton, as well as to measure the amount of translational or rotational misalignment.

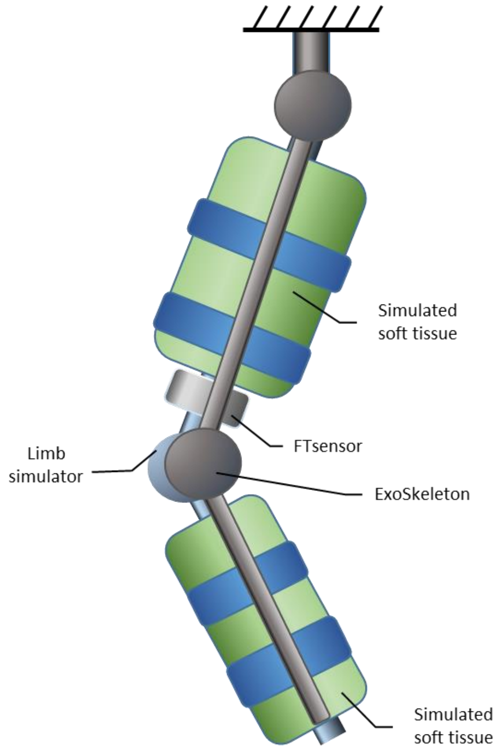

Figure 2: General structure of an appropriate test arrangement

Multiple flexing motions will be performed using this configuration, while collecting force and torque data as well as motion information of the instrumented limb* segments as well as from the exoskeleton segments. The same procedure will be repeated when the instrumented limb* is fitted with the maximum allowed translational offset, specified by the manufacturer, as well as the, by the manufacturer specified, maximum allowed rotational offset of the exoskeleton flexion joint axis relative to the flexion axis of the instrumented limb*. A rotational misalignment of more than 30 degrees can usually be considered non-realistic. The maximum translational or rotational offset should be applied in any direction that is realistically possible, unless it can be reasoned that testing is done in situations that already represent worst case situations.

During all the motions during the test the sensor data of the instrumented limb* will be recorded and synchronized with the motion capture data. From this sensor data relevant forces and torques that may appear in the joint can be calculated.

4.2.1 Data Acquisition

Data acquisition should be done using suitable acquisition rates. Since tests will be performed under normal motion speeds, an acquisition rate of 100 frames per second for the optical motion capture system will be sufficient. Spatial accuracy of the motion capture data should be within 2 mm. Angular accuracy, which will depend on the spatial accuracy, the marker placement and the inter marker distances, should be within 2 degrees. Marker data can be filtered with a 2nd order, zero phase low pass Butterworth filter with a cut-off frequency of no less than 10 Hz.

To allow for signal processing on the sensor data from the instrumented limb* an acquisition rate of at least 500 samples per second is advised. Signals can be filtered using a 2nd order, zero phase low pass Butterworth filter with a cut off frequency of 100 Hz.

Synchronization accuracy between the optical motion system and the sensor data from the instrumented limb* should be about one frame of the optical motion capture system. (usually about ±10 msec.)

5 Procedure

5.1 Test Plan

During the tests the internal force and torques in the instrumented limb* must be continuously recorded during each test trial, as well as the motions of the exoskeleton and the instrumented limb*.

5.2 Preparation

5.2.1 Test Arrangement

For preparing the validation setup:

- Make sure that the environmental conditions such as lighting are appropriate for the measurement technique you are using.
- Make sure all electronics of the measurement systems have warmed up, so readings are from stable sensors
- Calibrate the motion capture system as described in its user manual or check existing calibration where applicable. Make sure the calibration accuracy meets the required accuracy for measurement of the amount of translational or rotational misalignment.
- Mount the instrumented limb in the exoskeleton type RACA robot*
- Connect the sensors from the instrumented limb to the data acquisition system
- Make sure the data synchronization solution is active
- Make sure the RACA robot* is positioned within the capture range of the motion tracking (e.g. 3D electro-optical measurement) system and that its movements are not impaired by any obstacle.
- Position the instrumented limb in the RACA robot* and align it according the manufacturer's instructions on how to fit an exoskeleton to a human.

5.2.2 System Conditions

The system should be configured as in normal use situations.

5.2.3 Environmental Conditions

As stated in paragraph 3.3 no environmental conditions are expected to influence the test results.

5.3 Test Execution

Validation tests for translational misalignment:

- [step t1].Check that the instrumented limb* is installed according to the instructions of the manufacturer.
- [step t2] Start the data acquisition on the measurement systems
- [step t3] If needed apply a synchronization signal
- [step t4] Instruct the exoskeleton to flex the joint 10 times
- [step t5] If needed apply a synchronization signal
- [step t6] Stop the data acquisition

- [step t7] position the instrumented limb* in the exoskeleton so the flexion axis of the instrumented limb* is at 50% of the max. specified amount of allowed translational misalignment below the flexion axis of the exoskeleton
- [step t8] repeat step 2 – 6
- [step t9] position the instrumented limb* in the exoskeleton so the flexion axis of the instrumented limb* is at the maximum specified amount of translational misalignment below the flexion axis of the exoskeleton
- [step t10] repeat step 2 – 6
- [step t11] position the instrumented limb*in the exoskeleton so the flexion axis of the instrumented limb* is at 50% of the max. specified amount of allowed translational misalignment above the flexion axis of the exoskeleton
- [step t12] repeat step 2 – 6
- [step t13] position the instrumented limb*in the exoskeleton so the flexion axis of the instrumented limb* is at the maximum specified amount of translational misalignment above the flexion axis of the exoskeleton
- [step t14] repeat step 2 – 6

Validation tests for rotational misalignment:

- [step r1].Check that the instrumented limb* is installed according to the instructions of the manufacturer.
- [step r2] Start the data acquisition on the measurement systems
- [step r3] If needed apply a synchronization signal
- [step r4] Instruct the exoskeleton to flex the joint 10 times
- [step r5] If needed apply a synchronization signal
- [step r6] Stop the data acquisition
- [step r7] Check that the instrumented limb* is installed according to the instructions of the manufacturer.
- [step r8] position the instrumented limb* in the exoskeleton so the flexion axis of the instrumented limb* is “internally” rotated, relative to the flexion axis of the exoskeleton, to 50% of the maximum allowed rotational misalignment.
- [step r9] repeat step 2 – 6
- [step r10] position the instrumented limb* in the exoskeleton so the flexion axis of the instrumented limb* is “internally” rotated, relative to the flexion axis of the exoskeleton, to the maximum allowed rotational misalignment.
- [step r11] repeat step 2 – 6
- [step r12] position the instrumented limb* in the exoskeleton so the flexion axis of the instrumented limb* is “externally” rotated, relative to the flexion axis of the exoskeleton, to 50% of the maximum allowed rotational misalignment
- [step r13] repeat step 2 – 6
- [step r14] position the instrumented limb* in the exoskeleton so the flexion axis of the instrumented limb* is “externally” rotated, relative to the flexion axis of the exoskeleton, to the maximum allowed rotational misalignment

5.4 Data Analysis

Since direct measurements of torques in the joint are not easily done, a FT sensor is used to measure torques and forces at a location with a fixed position to the joint, as shown in Figure 3.

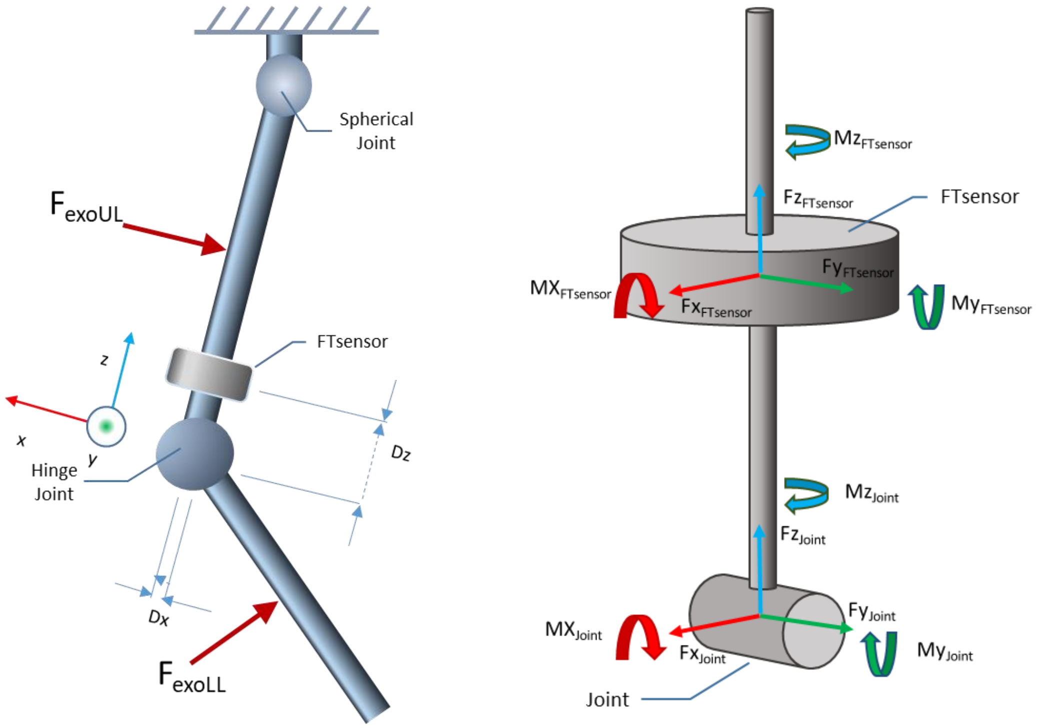

Figure 3: Schematic representation of the instrumented limb (left) and the placement of FTsensor in the upper segment of instrumented limb* (right)*

From the known location of the FT sensor relative to the joint the forces and torques in the FT sensor can be transferred to the location of the joint with

$$Fx_{joint} = Fx_{FTsensor} + \frac{My_{FTsensor}}{Dz} + \frac{Mz_{FTsensor}}{Dy}$$
$$Fy_{joint} = Fy_{FTsensor} - \frac{Mx_{FTsensor}}{Dz} + \frac{Mz_{FTsensor}}{Dx}$$
$$Fz_{joint} = Fz_{FTsensor} - \frac{My_{FTsensor}}{Dx} + \frac{Mx_{FTsensor}}{Dy}$$

and

$$Mx_{joint} = Mx_{FTSensor} + \ Dz\ Fy_{FTsensor} - Dy\ Fz_{FTsensor}$$
$$My_{joint} = My_{FTSendor} - Dz\ Fx_{FTsensor} + Dx\ Fz_{FTsensor}$$
$$Mz_{joint} = Mz_{FTsensor} - Dx\ Fy_{FTsensor} + Dy\ Fx_{FTsensor}\ ,$$

where Dx, Dy, Dz describe the displacement of the FT sensor relative to the center of the joint, described in the coordinate system of the proximal joint segment. In the instrumented limb* the FT sensor is mounted in the proximal joint segment.

5.5 Report

The following data needs to be present in the documentation:

- Description of the RACA* robot validated with this protocol
- Description of the motion capture system used
- Description of the instrumented limb used
- Robot speeds under which the tests were performed
- Maximum joint flexion used during experiments
- Load applied to the robot
- System conditions (normal, single fault)
- Description on the amount of translational or rotation misalignment applied

For each test sequence the following should be reported:

- measured maximum forces, torques
- interaction forces and/or pressures should be reported.

6 Bibliography

EN-ISO 13482:2014

ISO 14971:2019

EN-IEC 60601-1:2006

EN-IEC 80601-2-78:2020

EN-IEC 62366-1:2015

COVER
safearoundrobots.com

7 Annexes

7.1 Annex A – Test form Protocol EXO-MPA-1

Maintain proper alignment for joint axis alignment in hinge type joints

Testform - Protocol HC-EXO-MPA-1			
Test date		**Name of tester:**	
Sequence ID (Seq#)		**Hazard ID**	
Description of RACA* robot under validation			
Measurement system used:			
Calibration date:		**Measurement accuracy:**	
Instrumented limb used:			
- Proximal segment	Yes / No	**Acquisition rate (/s)**	
- Distal segment	Yes / No		
Rotationally aligned in transverse plane	Yes / No	**If no, specify amount of rotation (deg) / % of max** (+ = exo-rotation of limb in exoskeleton)	
Translationally aligned	Yes / No	**If no, specify amount of translation (mm) / % of max** (+ = upward translation of limb in exoskeleton)	
Condition	Normal/S.F.C.*	**Description (S.F.C.*):**	
Set maximum motion velocity (deg/sec)			
Set maximum joint flexion angle (deg)			

Target Metric				
Max Fx (N)		**Max vertical translation (mm)**		
Max Fy (N)				
Max Fz (N)		**Max axial rotation (deg)**		
Max Mx (Nm)				
Max My (Nm)				
Max Mz (Nm)				

Test ID (Seq#-id)	Max Fx	Max Fy	Max Fz	Max Mx	Max My	Max Mz	Pass? (T/F)
Max flexion angle:			Motion velocity:				
Remarks:							
Seq#-ID							Pass?
Max flexion angle:			Motion velocity:				
Remarks:							
Seq#-ID							Pass?
Max flexion angle:			Motion velocity:				
Remarks:							
Seq#-ID							Pass?
Max flexion angle:			Motion velocity:				
Remarks:							
Seq#-ID							Pass?
Max flexion angle:			Motion velocity:				
Remarks:							
Seq#-ID							Pass?
Max flexion angle:			Motion velocity:				
Remarks:							
Seq#-ID							Pass?
Max flexion angle:			Motion velocity:				
Remarks:							
Seq#-ID							Pass?

Max flexion angle:			**Motion velocity:**				
Remarks:							
Seq#-ID							**Pass?**
Max flexion angle:			**Motion velocity:**				
Remarks:							
Seq#-ID							**Pass?**
Max flexion angle:			**Motion velocity:**				
Remarks:							

Final Information about test

Date of testing	
Name of tester	
Overall conclusion	
Signature	