Being safe around collaborative and versatile robots in shared spaces

Protocol

Test Torque Limitation for a Restraint Type Robotic Device Acting on a Single Human Joint

ROB-LRE-1

The purpose of this protocol is to validate the safety skill Limit Restraining Energy for a robotic device acting on a single human joint along one degree of freedom. In this document the safety skill protects the user of a robotic device from excessive torques applied to a joint. The validation experiment is performed using a 1D force sensor and a testing frame placed around the robotic device. The torque generated by the robotic device is derived from the measured force.

This protocol is based on a safety test protocol developed in the COVR funded FSTP project SAFEharbor, by Amsterdam VUMC, TU Delft and LUMC and was published as Deliverable D1.4 for that project.

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

COVR is a community effort and values any honest feedback to our services. Please feel free to express your opinion about this protocol. The feedback form is only one click away. Thanks for making COVR even better!

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1 Introduction

The purpose of this protocol is to test the mechanical safety of a single-joint RACA* robot used for rehabilitation purposes, e.g. where mechanical perturbations on a single joint are applied. In this protocol, two separate torque limits are validated:

- A so-called position mode where the device is required to withstand a torque generated by the subject.
- A so-called torque mode, where the device can generate a torque to move an attached body segment of the subject. In this case, the maximum torque will be limited to keep this torque within a physiologically safe range. This maximum torque limit can be either set manually or detected automatically.

Validation of the safety skill "Limit restraining energy" for a restraint type robotic device acting on a single human joint is executed by testing whether the imposed torques and angles on the joint do not exceed the pre-defined limits according to the system, and whether the imposed torques stay within physiologically acceptable thresholds.

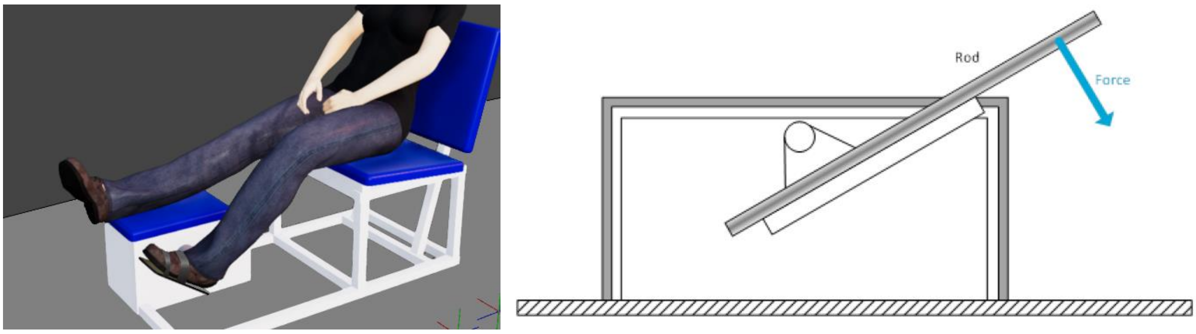

Figure 1: A- Leg in perturbating robot *B: Test setup*

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	Limit Restraining Energy : Limit torque range in physical interaction between robot and patient.
System	Robot arm – rehabilitation RACA* robot for use with human hinge joint
Domain	Healthcare
Conditions	-
Measurement Device(s)	1D Force sensor

⚠	**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

Actuated applied part (source: IEC 80601-2-78:2019 201.3.201)
intended to provide actively controlled physical interactions with the patient that are related to the patient's movement function, to perform a clinical function of a RACA Robot

Emergency stop (source: IEC 80601-2-78:2019 201.3.206)
manually initiated interruption of operation intended to stop the RACA robot to prevent harm

Mechanical hazards associated with support systems (IEC 80610-2-78:2019 201.9.8)
compensation of the actuated applied parts. Hazard associated with the support system for the patient

Position mode (source: local to the document)
a mode where a torque is generated to keep the joint in a fixed position counteracting a torque generated by the subject and/or by gravity

Protective stop (source: IEC 80601-2-78:2019 201.3.210)
the interruption of operation automatically initiated by the RACA Robot, that allows a cessation of motion for basic safety and essential performance purposes. (in contrast to ISO13482:2014, safety requirements for personal care robots, which allows both manual and automatic initiation)

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

Robot (source: ISO 8373:2012 2.6)
actuated mechanism programmable in two or more axes with a degree of autonomy, moving within its environment, to perform intended tasks

Robotic device (source: ISO 8373:2012 2.8)
actuated mechanism fulfilling the characteristics of an industrial robot or a service robot, but lacking either the number of programmable axes or the degree of autonomy

RoM (source: local to the document)
Range of motion – in this document it refers to the angular range over which a human joint can flex

Torque mode (source: local to the document)
a mode where a torque is generated to keep the joint in a fixed position counteracting a torque generated by the subject and/or by gravity

2 Concept and Objectives

The concept of the validation is to test the maximum torque (safety) settings at various angles for a robot acting on a single human joint. This maximum torque setting limits all potential torques for that human joint, i.e. the voluntary and involuntary inertial, viscous and spring forces of the human joint during acceleration, velocity and position variation of the human joint. The safety limit should work within the manually pre-set range of motion of the human joint which is tolerated by the subject. The safety skill should be tested in two control modes (when applicable), i.e. position mode*, where the device has to withstand a torque applied by the human subject, and a torque mode*, where the torque applied by the robotic device on the human joint has to be limited to a pre-set maximum torque.

2.1 Hazardous Situations

In position mode* failure to withstand the maximum torque applied by the subject may cause the device to fail. This may result in an unintended sudden motion, that may result in stress on the joint.

In torque mode*, the manipulator should not exceed torques during a motion (within a pre-set RoM) resulting in conditions that are not tolerated by the subject (experienced as uncomfortable or painful, or even causing damage to the soft tissue or the joint).

2.2 Target Behavior and Metrics of the Safety Skill

In position mode* the target behaviour of the safety skill to be validated is that the robotic device can withstand torques applied by the human subject or, should a torque generated by the human exceed the torque limits of the robotic device, this should not result in a hazardous motion. The maximum allowable torque (T_{maxM}) has to be specified by the manufacturer.

In torque mode* a maximum torque T_{maxU} (lower than T_{maxM}) is set as the reference torque during the validation experiments. The target behavior of the safety skill to be validated in this torque mode is not exceed the maximum pre-set torque T_{maxU}.

Relevant limit values for T_{maxU} can be found in literature (e.g. Anderson et al 2007, Hahn et al 2011) and/or can be derived from recorded data by Amsterdam UMC, Leiden UMC and TU Delft, which is listed in Annex B.

In position mode* the target metric is:

- Maximum Measured $T_{Applied} <= T_{maxM}$
- Controlled behavior (i.e. no sudden release/fast movement) of the robotic device, in case of failure when$T_{Applied} < T_{maxM}$. In this procedure the controlled behavior will be tested by observation. However, it can also be determined using an accelerometer to quantify the behavior as the maximum allowed angular acceleration.

In torque mode* the target metric is:

- Maximum Measured $T_{Applied} <= T_{maxU}$

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 §7.3 (Annex C).

3.1 System

If the system consists of more than one joint, the configuration of the joints, not involved in the single joint validation, should be reported.

Since straps, cuffs etc. may reduce the effective torque in the human joint, the tests should be performed under a worst case condition. A rod, representing the involved human body segment, should be fixated to the robotic device to maintain the correct position of the human joint relative to the robotic joint.

If it is to be expected that any changeable parts of the system may have effects on the safety of the entire system, the protocol user must consider those changeable parts as different system-related conditions. These should be reported for every single test using the form in §7.3 (Annex C).

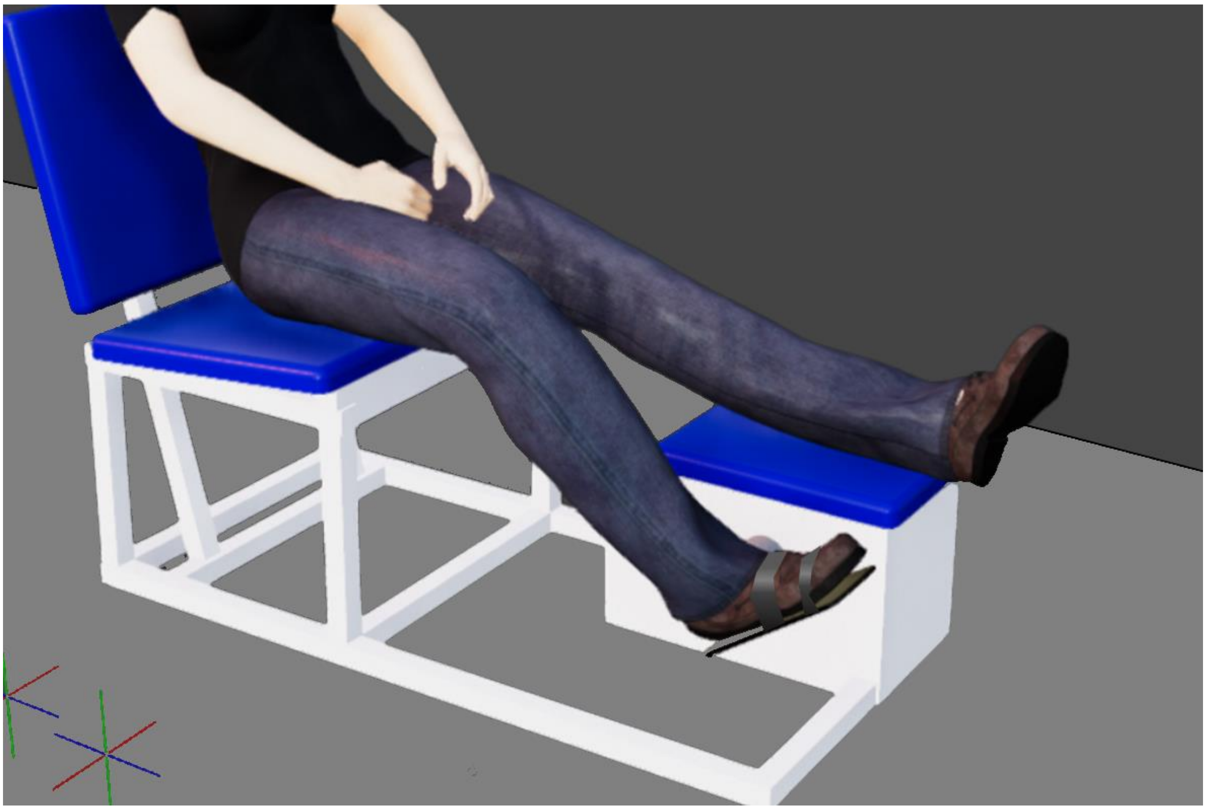

Figure 2 Example of use setup of a robotic device this protocol refers to, with the subject's foot strapped to the foot plate, which is attached to the motor of the robotic device

If relevant different operation modes can be expected, i.e. position mode* and torque mode*. The single actuated joint in the system can either actively counteract a torque applied by a human subject (position mode*) or generate a limited torque that will result in a movement in the joint of the human subject (torque mode*).

- In position mode* the system should be able to withstand torques up to the maximum torque T_{maxM}, as specified by the manufacturer. To validate the safety skill here is to validate whether the maximum torque can be counteracted and possible failure does not result in undesirable fast motions.
  For this position mode* the maximum torque T_{maxM} should be recorded in the test form in Annex 7.3
- In torque mode* the system should limit the applied torque during a motion where the applied torque $T_{Applied}$ does not exceed T_{maxU}.

For pragmatic reasons the torque mode* test can be performed under (quasi-)static conditions. According to literature (e.g. de Vlugt et al. 2010) this is valid if inertial and gravitational forces are low relative to the stiffness forces at the end-points of the RoM. (As a rule of thumb: if inertial and gravitational forces are less than about 20% of the stiffness forces at the extremes or the motion).

The system mode for which the validation experiments are executed should be reported for every experiment in the form in §7.3 (Annex C)

This protocol does not consider additional conditions when the robotic device is mounted on a support structure, e.g a mobile platform, that may have an additional influence on the safety of the robotic device.

3.2 Environment

The environment in which such a robotic device is intended to be used and for which this protocol is developed will have to be defined. Usually this will be an indoor room.

The protocol must consider that movements of the robotic device are not restricted by any obstacle in its surrounding.

3.3 Miscellaneous

For medical devices single fault conditions (S.F.C.) may impact the safety skill. Therefore a thorough analysis of potential relevant S.F.C.'s must be performed. The tests should be executed under those relevant S.F.C.'s as well and the specific S.F.C. should be reported in the form in §7.3 (Annex C).

4 Test Setup

4.1 Sensing devices

A linear 1D force sensor is used to measure the tensile force in the rope. This force sensor for the test described in this protocol should have a range that is sufficient to measure at least 1.2 times the maximum force required, in combination with the chosen moment arm, to generate the maximum torque required to validate the safety skill. Accuracy of the force sensor used must be better than 2% of the maximum force needed to generate the maximum allowable torque in position mode* T_{maxM}. The frequency range of the 1D force sensor should be at least 100 Hz

The sensing devices used, including a reference to the calibration, must be reported in the form in §7.3 (Annex C)

When possible, the torque and angular position sensors in the robotic device can be measured as additional data.

4.2 Method

For validation of the safety skill in position mode*, a rod is attached to the interface where the subject would be attached to the robotic device, perpendicular to the rotation axis of the human joint (Figure 3**Error! Reference source not found.**).

- The attachment of the rod should be rigid, simulating a worst-case situation, where there is no compliance in the connection between the robot and the rod.
- The rod is connected to a force sensor via a non-elastic rope.
- The distance L between the center of rotation of the robotic device and the "line of action" of the force through the force sensor should be measured at the start of the experiments.

- The other side of the force sensor is connected to a platform for bearing weights via a pulley system.
- During the validation experiment forces can be applied by adding weights to the weight bearing platform
- The robotic device should maintain a fixed position under external load. The torque can be validated calculating the product of the measured force by the force sensor distance to the “line of action” L (see Figure 3).

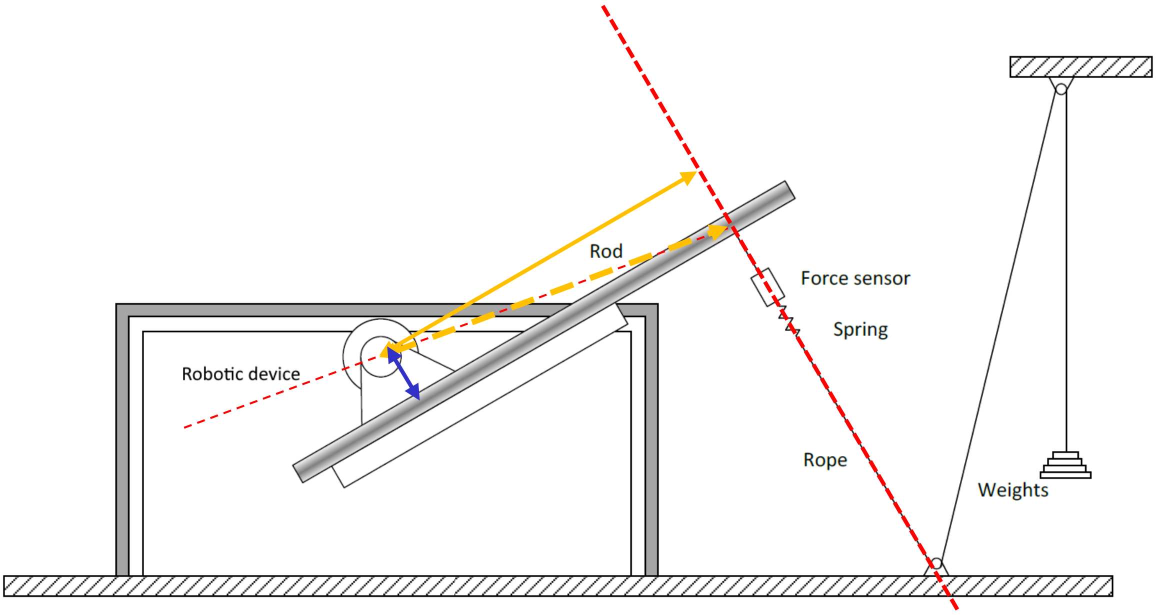

Figure 3 Position mode arrangement showing the interface plate of the robotic device attached to a rod connected to a force sensor. The torque is applied via the weights.*

The spring in the position mode* setup (Figure 3**Error! Reference source not found.**) is used to dampen the force peak that may result from placement of the test weights. Therefor the k-factor might be lower than the one used in the torque mode* measurements. However, use of these springs in the measurement setups is not strictly required.

In the torque mode* test arrangement (Figure 4) a rod is attached to the interface where the subject would be attached to the robotic device, perpendicular to the rotation axis of the human joint.

- The attachment of the rod should be rigid, simulating a worst-case situation, where there is no compliance in the connection between the robot and the rod.
- The rod is connected to a force sensor via a non-elastic rope.
- The other side of the force sensor is connected to the floor (or another unmovable object) via a non-elastic rope.
- The distance between the center of rotation of the robotic device and the “line of action” of the force through the force sensor should be measured at the start of the experiments. During the validation experiment the robotic device will apply a requested torque tensioning the rope. The torque can be validated calculating the product of the measured force by the force sensor distance L to the “line of action” of the force through the force sensor (see Figure 4).

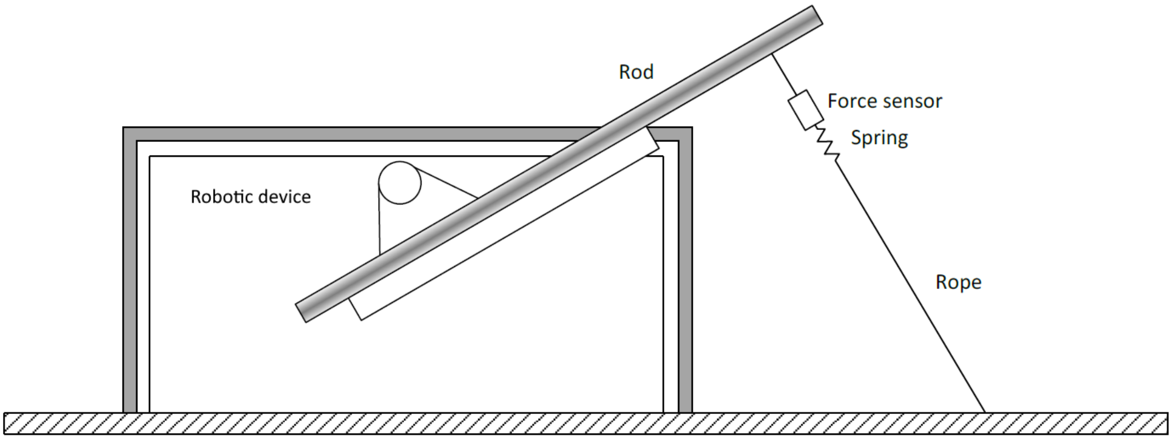

Figure 4 Torque mode arrangement showing the interface plate of the robotic device attached to a rod connected to a force sensor attached to the floor. The torque is applied by the robotic device, which can then be validated using the force sensor.*

The spring in the torque mode* setup (Figure 4**Error! Reference source not found.**) should be relatively stiff, e.g. a k-factor of at least 20% of the maximum force to apply/mm. However, use of the spring in the measurement setups is not strictly required.

The tensile strength of the rope as well as the attachment methods at the different attachment points should be chosen such that these will not fail at forces of at least 1.2 times the expected maximum force values.

For the experiments in both modes, both the force sensor data and the angle of the rod relative to the floor should be measured continuously. This angle can be used both to monitor any (un)intended movements.

4.2.1 Data Acquisition

The 1D force sensor data should be sampled with a sampling frequency of at least 10 Hz.

Since the angular position sensor is used to monitor whether unexpected movements will occur, this sensor should be sampled with a sampling rate suitable to ensure a reliable detection of such an event.

Since during the validation experiments, both in position mode* as well as in torque mode*, no (significant) movements are expected during normal operation, the distance between the axis of the joint and the attachment point of the rope to the rod can be measured once. This measurement has to be re-done, should the orientation of the rod or the attachment point of the force change. Also, changes in the angle between the rod and the direction of the measured force in the force sensor should be recorded as well.

The sampling frequencies for each of the sensing devices, the distance from the moment arm length and the angle between the measured force direction as well as the angle between the rod and the force direction must be reported in the form in §7.3 (Annex C)

4.3 Data Analysis

Measured forces can be filtered to remove any measurement noise. The bandwidth of the force signal should remain between 0 and 2 times the controller update rate.

The "measured" torque $T_{Applied}$ must be calculated: $T_{Applied} = F_{Measured} \times L$

Where: L is the moment arm between the axis of the joint and the point of application of the force

$F_{Measured}$ is the measured force, corrected for the angle between the direction of the measured force and the moment arm L.

5 Procedure

5.1 Test Plan

To validation of the limit restraining energy safety skill of the robotic device in position mode*:

- The robotic device is set to maintain a set angle.
- By adding weights to the rope/pulley system external torques are applied (see Figure 3**Error! Reference source not found.**). The robotic device should be able to counter the external torques as long as these are below the specified max internal torque limit T_{maxM}.

For validation of the safety skill in torque mode*:

- A small torque will be applied by the robotic device to pre-tension the rope (see Figure 4)**Error! Reference source not found.**. Once in equilibrium, the robotic device (internal) torque is increased, preferably according to a linear incremental ramp profile. The robotic device should limit the applied torque as soon as the internal torque profile might exceed the pre-set torque limit T_{maxU}.

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 give instructions on how to prepare each part of the setup and all conditions with a significant influence on the target metrics. Each test case must be documented using the form in §6.3 (Annex C). This also includes the identified conditions and their values.

5.2.1 Test Arrangement

Rod

- Install the rod on the foot plate.

Force Sensor

- For position mode* (see Figure 3):
    - Position the frame with the pulleys guiding the rope used to transfer the forces from the force sensor to the plate where the weights can be placed.
    - Attach one side of the force sensor to the rope that is attached to the platform where the weights can be placed.

  - Attach the other side of the force sensor to the rope that is attached to the rod. For easier calculation and better sensitivity make sure the angle between the rod and the rope with the force sensor is about 90° (± 5°)
  - Measure the moment arm L (see Figure 3).
- For torque mode* (see Figure 4):
  - Attach one side of the force sensor to the rope that is attached to the floor (or any other point that maintains the same spatial position to the robotic device).
  - Attach the other side of the force sensor to the rope that is attached to the rod. For easier calculation and better sensitivity make sure the angle between the rod and the rope with the force sensor is about 90° (± 10°)
  - Measure moment arm L (see Figure 4).

Angular position sensor

- Attach the angular position sensor to the rod to monitor any significant motions

Measurement Equipment

- Connect all sensors to the A/D acquisition device.
- Make sure that the recording of all signals can be started and stopped.

5.2.2 System Conditions

The protocol user must configure the robotic device in the exact way it will run later. Should this require specific instructions, these instructions should be followed.

5.2.3 Environmental Conditions

There are no specific environmental conditions mandatory for the tests. However, it is recommended that the tests are run in the same environment and conditions as the robotic device will operate in.

5.3 Test Execution

5.3.1 Position mode* test

Apply the following steps for the position mode* test:

- Prepare the setup as described for position mode* in §**Error! Reference source not found.**
- Set the robotic device in the mode for holding position.
- Start the data acquisition
- Increase the external torque by adding weights until the maximum device torque T_{maxM} is reached.
- Stop the data acquisition
- Perform at least 2 trials.

5.3.2 Torque mode* test

Apply the following steps for the torque mode* test:

- Prepare the setup as described for torque mode* in §**Error! Reference source not found.**
- Set a user limit T_{maxU} for the torque the device will be is allowed to generate
- Start the data acquisition
- Setup a linear increment ramp build-up for the internal torque until T_{maxU}.is reached.
- Stop the data acquisition

- Perform at least 2 trials with this setting.
- Repeat this test for at least 3 different settings for T_{maxU}.

5.4 Data Analysis

When applicable, there should be results from two tests, i.e. from the tests in torque mode* and from the tests in position mode*.

The force sensor measures force while the robotic device generates the torque. The data from the force sensor then needs to be converted to the actually applied torque:

$$T_{Applied} = F_{Measured} \times L$$

Where: L is the moment arm between the axis of the joint and the point of application of the force

$F_{Measured}$ is the measured force.

For the test in position mode*:

- The robotic device should be able to withstand external torques up to T_{maxM}. Failing to do so, e.g. resulting in sudden, possibly fast and potentially hazardous movements, is considered a fail.

For the tests in torque mode*:

- The robotic device should limit the applied torques to the set T_{maxU}. Failing to do so, resulting in an applied torque higher than the set T_{maxU} is considered a fail. Also, when a sudden release of the applied torque could result in a potentially hazardous movement, such a sudden release of the applied torque should also be considered a fail.

5.5 Report

Use the Test Evaluation form in Annex C (§7.3) to report the test configuration and the results of the tests.

6.3 Annex C: Test evaluation form – Limit Restraining Energy for single hinge joint

Test and device description

Test ID / Test no	
Description/location	
Date of test	
Test operator ID	
Robotic device	
Model	
Manufacturer	
Photo test setup	
Conditions	
Environmental conditions description	

S.F.C.	Y / N	Description	

Setup configuration

Force sensor	
Manufacturer and type	
Calibrated range	
Relative error (linearity)	
Miscellaneous	
Angle sensor	
Manufacturer and type	
Calibrated range	
Relative error (linearity)	
Miscellaneous	

Acquisition Configuration			
Sampling frequency (Hz)		ADC resolution	
System Configuration			
Rod Size (m)		Moment arm (m)	

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Position mode* test:

	Test 1	Test 2
Max torque T_{maxM} (Nm)		
Moment Arm (m)		

Test Result

	Test 1	Test 2
Maximum force (N)		
Effective torque (Nm)		
Significant motion detected (Y/N)		

Summary

	Test 1	Test 2
Pass/Fail		

Torque mode* test

Sequence #	☐ 1		☐ 2		☐ 3	
	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Max set torque T_{maxU} (Nm)						
Moment Arm (m)						

Test Result

	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Maximum force (N)						
Effective torque (Nm)						
Significant motion detected (Y/N)						

Summary

	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Pass/Fail						

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6 Bibliography

Anderson, Madigan, Nussbaum (2007) Maximum voluntary joint torque as a function of joint angle and angular velocity: Model development and application to the lower limb. Journal of Biomechanics 40: 3105–3113

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Sloot LH, van der Krogt MM, de Gooijer-van de Groep KL, van Eesbeek S, de Groot J, Buizer AI, Meskers (2015) The validity and reliability of modelled neural and tissue properties of the ankle muscles in children with cerebral palsy. Gait Posture 42(1):7-15.

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van der Krogt H, Kouwijzer I, Klomp A, Meskers CGM, Arendzen JH, de Groot JH (2019). Loss of selective wrist muscle activation in post-stroke patients. Disabil Rehabil. 11:1-9.

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7 Annexes

7.1 Annex A: Adaptation for robotic devices acting on a single joint in a non-vertical plane.

For devices acting in a non-vertical plane a similar test setup as used for a device working in a vertical plane can be used, but then the actuator has to be rotated in such a way that it will work in the vertical plane or the acting forces have to be transferred from the normal working plane to the vertical plane via a pully system. Special attention should then be paid to possible additional forces in the system due to friction as well as possible measurement error due to insufficient stiffness in the test setup.

7.2 Annex B: Example reference values for maximum joint torques

This annex contains reference values for torques to be applied about the ankle in typically developing (TD) children and children with cerebral palsy (CP), for a large age range. These data give an indication of what maximum torques were tolerated by the subjects. The data were collected using manual, instrumented testing at slow and fast stretching velocity. The torques represent the maximum torque applied by the experimenter towards the end range of motion. See Sloot et al. (2017) for measurement details.

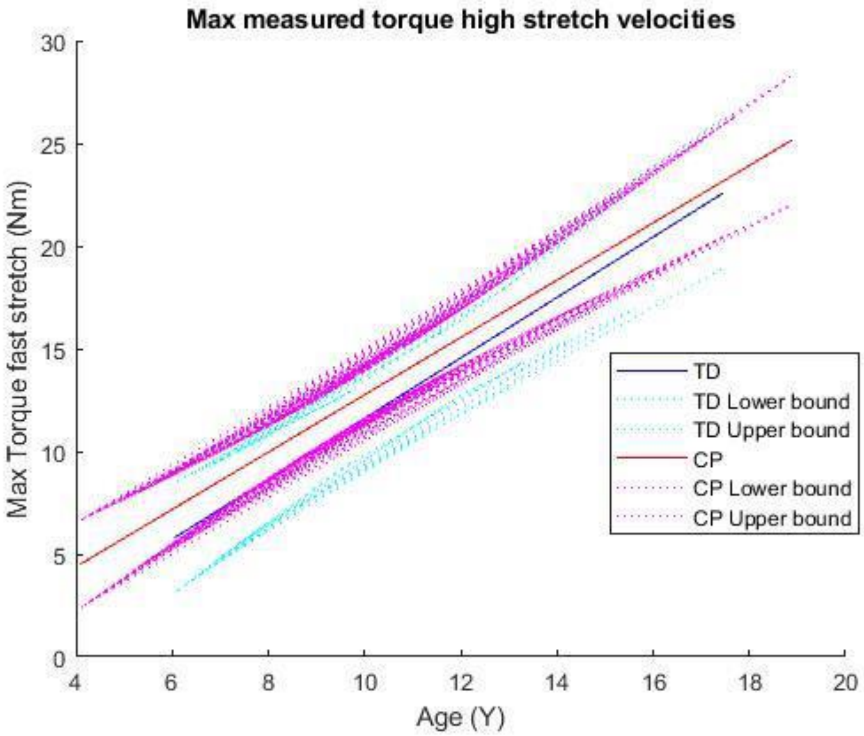

Figure 5 Max measured ankle torque high stretch velocities versus age TD: typically developing; CP: cerebral palsy (Sloot et al. 2017)

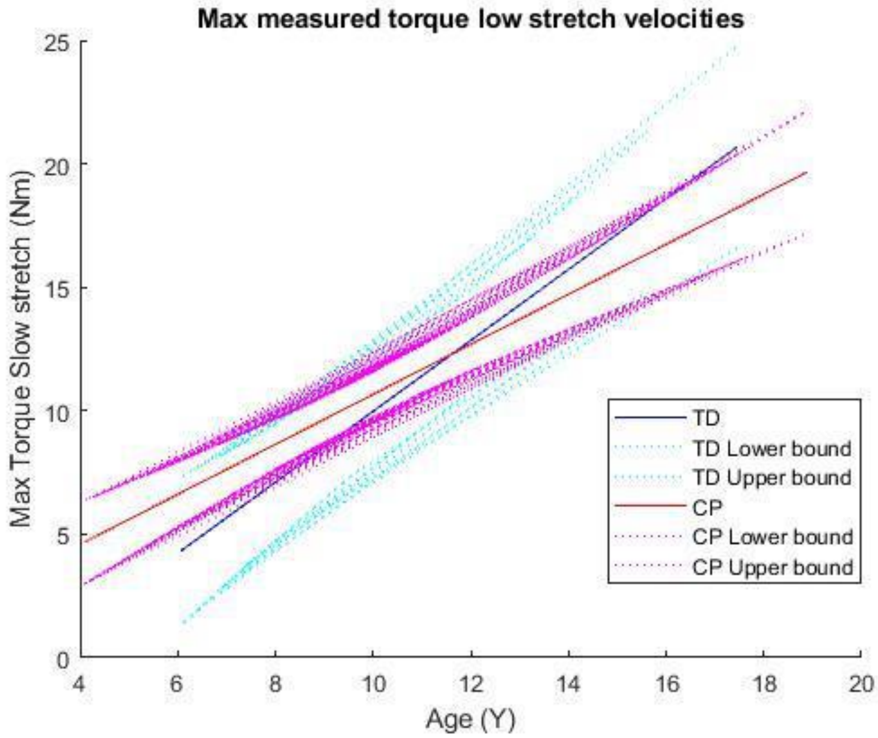

Figure 6 Max measured ankle torque at low stretch velocities versus age (Sloot et al. 2017)

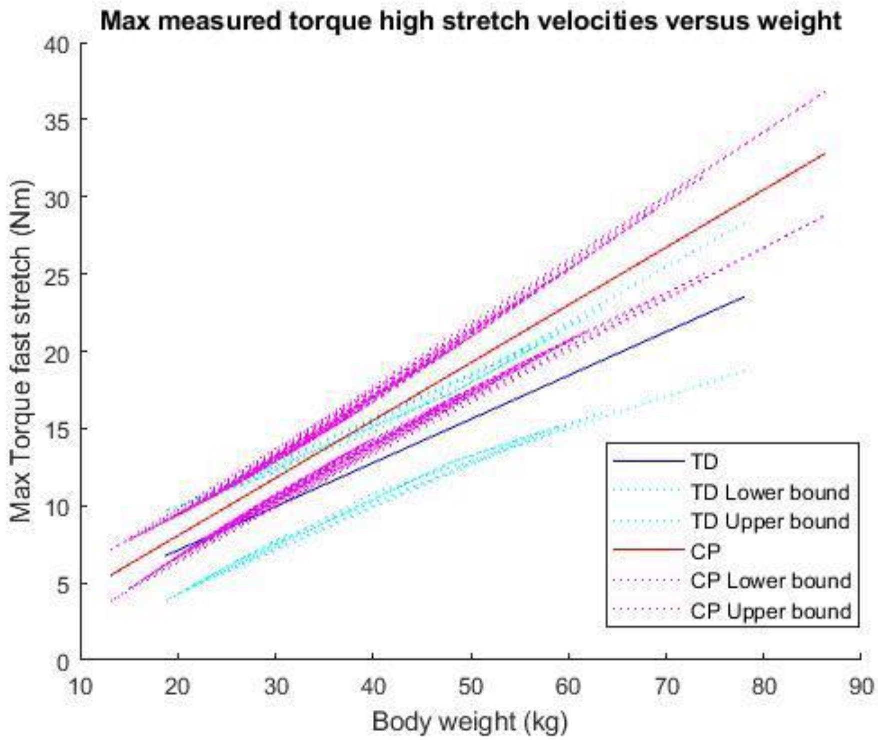

Figure 7 Max measured ankle torque at high stretch velocities versus body weight; TD: typically developing; CP: cerebral palsy (Sloot et al. 2017)

7.3 Annex C: Test evaluation form – Limit Restraining Energy for single hinge joint

Test and device description

Test ID / Test no			
Description/location			
Date of test			
Test operator ID			
Robotic device			
Model			
Manufacturer			
Photo test setup			
Conditions			
Environmental conditions description			
S.F.C.	Y / N	Description	

Setup configuration

Force sensor	
Manufacturer and type	
Calibrated range	
Relative error (linearity)	
Miscellaneous	
Angle sensor	
Manufacturer and type	
Calibrated range	
Relative error (linearity)	
Miscellaneous	

Acquisition Configuration			
Sampling frequency (Hz)		ADC resolution	
System Configuration			
Rod Size (m)		Moment arm (m)	

Position mode* test:

	Test 1	Test 2
Max torque T_{maxM} (Nm)		
Moment Arm (m)		

Test Result

	Test 1	Test 2
Maximum force (N)		
Effective torque (Nm)		
Significant motion detected (Y/N)		

Summary

	Test 1	Test 2
Pass/Fail		

Torque mode* test

Sequence #	☐ 1		☐ 2		☐ 3	
	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Max set torque T_{maxU} (Nm)						
Moment Arm (m)						

Test Result

	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Maximum force (N)						
Effective torque (Nm)						
Significant motion detected (Y/N)						

Summary

	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Pass/Fail						