COVR

Being safe around collaborative and versatile robots in shared spaces

Protocol

Test Exoskeleton for Limiting Physical Interaction Energy

EXO-LIE-1

The specific purpose of this protocol is to validate the safety skill "limit interaction energy" by measurement. The skill "limit interaction energy" protects bystanders from injuries caused by collision with the exoskeleton. This protocol is therefore not focusing on the safety of the person attached to the exoskeleton but rather of persons in close proximity of the exoskeleton. For the execution of this protocol it is required that the reader has a bio-fidelic force and pressure measurement device available.

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

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

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1 Introduction

The purpose of this protocol is to validate by measurement that the contact force and pressure, affecting a bystander during an unintended contact with an exoskeleton, do not exceed biomechanical limits, which apply to the considered case (for instance, those of ISO/TS 15066). This protocol is used for validating impact (transient contact) and clamping (quasi-static contact) collisions. The testing procedure involves a bio-fidelic instrument that the user must mount to a stiff frame (no freely moving masses).

Example: A patient is training in exoskeleton-type gait trainer with the therapist in close proximity. A typical case of foreseeable misuse is the therapist reaching spontaneously into the exoskeleton's trajectory. In such a situation, an exoskeleton part likely collides with the outstretched arm of the human. In case there are no physical constraints and the arm can move freely into the direction of the impact, the physical contact between robot and human will last only for a short duration and thus classified as transient. In case the exoskeleton clamps the therapist against a rigid object (e.g. the support structure of the gait trainer), the contact has also a quasi-static part in which the contact force remains on a constant level.

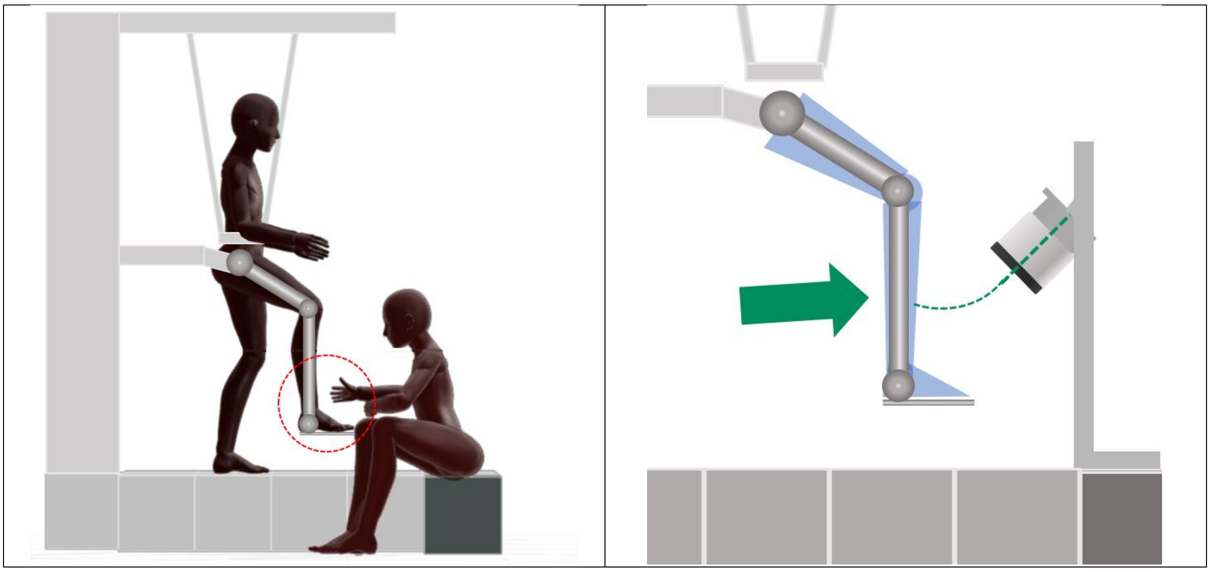

Figure 1: Exemplary situation of a transient contact (left) and the principle test setup to measure such contacts with a bio-fidelic instrument (right)

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	limit physical interaction energy
System	exoskeleton
Sub-System	n/a (no subsystem)
Domain	healthcare/rehabilitation or other
Conditions	No obstacles (transient contact); obstacles (quasi-static contact)
Measurement Device(s)	bio-fidelic measurement instrument that mimics the biomechanical behavior of the human body (at least of its considered part) and that can measure contact force and pressure

	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 have 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

(1) wearable device that augments, enables, assists, and/or enhances physical activity through mechanical inter-action with the body (ASTM F3323−19a)

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

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

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

Rehabilitation robot

See RACA robot. *Note: an Exoskeleton is one type of RACA robot / Rehabilitation robot*

Transient contact (source: ISO/TS 15066)

Contact between an operator and part of a robot system, where the operator body part is not clamped and can recoil or retract from the moving part of the robot system. In the course of the contact force recorded over time, the transient contact phase is the part of the signal that ranges from initial contact to 500 ms thereafter.

Quasi-static contact (source: ISO/TS 15066)

Contact between an operator and part of a robot system, where the operator body part can be clamped between a moving part of a robot system and another fixed or moving part of the robot system. In the course of the contact force recorded over time, the quasi-static contact phase begins 500 ms after initial contact.

2 Concept and Objectives

The concept of the validation process is to simulate an impact with a real exoskeleton and a bio-fidelic measurement instrument that mimics the biomechanical characteristics of the human body. During the test, the exoskeleton must operate under the same conditions, as it will be in its real application. The objective of the test is to validate by measurement whether the applied safety skill “limit physical interaction energy” prevents the exoskeleton from exceeding the applicable biomechanical limit values in accidental contacts with bystanders.

2.1 Hazardous Situations

Here, the term *hazardous situation* denotes an accidental contact (collision or clamping) between exoskeleton and human as introduced in Section 1. The protocol user must apply the guideline given by this document for every possible impact identified by the risk assessment as a case of foreseeable and potentially hazardous misuse.

	Suggestion
	The intended use and the foreseeable misuse, as identified by the risk assessment, can support to clarify the potentially hazardous situations. Losing consciousness or malicious mischief/vandalism are no typical cases of foreseeable misuse.

2.2 Target Behavior and Metrics of the Safety Skill

The target behavior of the skill "limit physical interaction energy" is to prevent the robot from exceeding the biomechanical limits specified in the risk assessment.

The target metrics are values based on physical and measurable quantities. They represent a threshold that the output values of the test must not exceed to pass the test successfully. For validating the robot skill "limit physical interaction energy," the output values are:

- Maximum collision force F_{TR} for transient contact phase
- Maximum collision pressure p_{TR} (normal stress) for transient contact phase
- Maximum collision force F_{QS} for quasi-static contact phase
- Maximum collision pressure p_{QS} (normal stress) for quasi-static contact phase

The target metrics shall be specified during the risk assessment. For this validation protocol, the target metrics are limits of the output values:

- Force limit $\hat{F}_{TR}$ for transient contact (maximum allowable impact force)
- Pressure limit $\hat{p}_{TR}$ for transient contact (maximum allowable normal impact stress)
- Force limit $\hat{F}_{QS}$ for quasi-static contact (maximum allowable clamping force)
- Pressure limit $\hat{p}_{QS}$ for quasi-static contact (maximum allowable clamping pressure)

The target metric can vary for different parts of the human body, so it is crucial to assure which metric value applies to which body part. The limits listed in ISO/TS 15066:2016 can serve as a guideline. However, note that these limits are intended to protect healthy factory workers. They are not valid for children or persons with health issues. This has to be considered in the risk assessment. Please report the values of the target metric for each test using the form in the Annex B.

Example: Endangered Body Part and Limit Values

Body Part	Force (N)		Pressure (N/cm²)		Stiffness (N/mm)
	QS	TR	QS	TR	
Forearm muscle	160	320	180	360	40
Source	ISO/TS 15066:2016				

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 on this plan. 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 B.

3.1 System

The term *system* refers to an exoskeleton typically consisting of segments, joints and cuffs. The segment speeds in combination with the applied load (attached limbs of the human) may affect the ability of the safety skill to mitigate the risk for bystanders. Also, the length and total mass of the exoskeleton segments might have an influence on the inertia and thereby on this safety skill. Therefore, the skill shall be validated:

- At maximum speed / angular velocity as specified by the manufacturer
- With maximum load as specified by the manufacturer
- At minimum and maximum segment lengths as specified by the manufacturer

A weighted dummy limb is additionally required that has to be attached to the exoskeleton. The dummy limb simulates the weight and center of mass of the maximum load as specified by the manufacturer. Alternatively, a weight of the same mass as the human body segment can be attached to the exoskeleton at the location of the segment's center of mass in normal use. Optional structures that can be mounted on the exoskeleton such as devices for toe lift can alter the contact surface during collision. All of these different system-related conditions must be considered.

Please report the system composition for every single test using the form in Annex B.

Example: System Configuration

Robot arm	
Manufacturer	The Exoskeleton Company
Model	Exo 10
System configuration	Safety Package
Control software	coControl, version 2.3.1
Mounted construction 1	
Manufacturer	The Exoskeleton Company
Model	footlifter 5
Short description	Foot lifter mounted to lower leg and foot segments of exoskeleton
Dummy limb(s)	
Manufacturer	My Company
Model / type	LegDummy2
Short description	20 kg weight, 88 cm length

When the safety skill takes over control, its configuration likely affects the robot behavior. Hence, it is also necessary to record the applied safety configuration in the form. Unfortunately, the robot manufacturers implement their safety functions and skills differently why there is no list to record the configured properties commonly. The protocol user must, therefore, record the available and activated configuration properties formlessly, including the assigned values. The following example shows how the formless recording can look. The support setting of the robot (100% guidance or patient /exoskeleton user in co-control) may also have an influence on the exoskeleton's behavior during collisions. Test in the worst-case condition or in several conditions where necessary.

Example: Applied safety configuration with direct impact on the safety skill

Safety Skill Properties	
Guidance	100 %
Speed limit	0.5 m/s
Torque limit axis 1	160 Nm

In addition to the configuration of the exoskeleton system, the state of the exoskeleton the moment the impact occurs also has a significant influence on the output values of the validation test. The following items describe the exoskeleton state:

- Joint configuration (axes position)
- Direction and magnitude of segment velocity (depends on the axes velocities)

For a proper validation test, it is necessary to establish the same exoskeleton state as the one the exoskeleton would have at the time of a potential impact, whereby the safety skill takes over control. Therefore, the point of interest for the test is the point of the robot path where an impact is most likely. The risk assessment should clarify the exact moment and position of this point. Therefore, the risk assessment is the primary source to identify the robot state for the test.

Every point along the exoskeleton trajectory corresponds to a specific segment position. The timeline of the trajectory implicates a segment velocity. The exoskeleton kinematics creates a relation between the position of the exoskeleton axes (joint space) and each point on the path the segment takes (workspace), so the axes positions correspond directly to the segment position. The protocol user needs to extract the exoskeleton segments' positions and velocities from the exoskeleton program. Please report both for every single test using the form in Annex B.

Example: System State

Configuration Space	**A1**	**A2**	**A3**	**A4**	**A5**	**A6**	**A7**
Axes position (deg)	11,9	0	0	0	0	0	
Axes velocities (deg/s)	60	30	-60	30	0	0	
Workspace	**ABS**	**X**	**Y**	**Z**			
Segment velocity (mm/s)	750	0	750	0			
Override (%)	100						

The user must derive appropriate test points on the exoskeleton trajectories from their risk assessment. These points should be related to cases of foreseeable misuse and other positions at which the robot is likely to collide with the human.

For this test protocol, single fault conditions that can have a significant impact on the outcome need to be considered. That can for example be the failure of a force or torque sensor. Repeat the test with all single fault conditions identified as relevant.

The exoskeleton considered in this protocol might be a subsystem of a larger training device (e.g. a stationary robotic gait trainer including the exoskeleton, a weight support and a treadmill. If any of those sub-systems introduce additional hazards as identified in the risk assessment, perform the test with those sub-systems in place and test the collision in the identified hazardous situations.

3.2 Environment

The protocol user must consider (and arrange, if applicable) the following environmental conditions for the validation tests:

- No obstacles (endangered part of the human body is spatially unconstrained and can move freely following the direction of the contact force)
- Obstacles (endangered part of the human body is spatially constrained and cannot move freely into the direction of the contact form)

3.3 Miscellaneous

Other relevant conditions are:

- Location of the contact area on the exoskeleton (according to the risk assessment)
- Endangered body parts (parts of the human body the robot can affect; see Section 2.2)

Use the form of Annex B to record the location and shape of the contact area on the robot structure that is under test.

Example: Misc. Conditions

Contact Area (on exoskeleton)	
Location	Lower leg segment (frontal face of orthosis)
Photo	(insert a photo here)

Report for each endangered body part the stiffness it has under a load equal to the limit value. Given the layered composition of human tissue, reference literature for limit values might distinguish between separate values for the stiffness of the soft tissue and the stiffness of the bone (see example in Section 2.2). Annex A presents a list with stiffness parameters for some parts of the human body.

4 Test Setup

4.1 Equipment

The following sensors are required to record the contact force and pressure during the validation test:

- Load-cell for force measurement over time
- Foil sensor for pressure measurement over time

The load cell to measure the contact force must fulfill the following requirements:

	Minimum	**Recommended**
Number of axes	1	1
Calibrated range	0 … 300 N	0 … 1000 N
Relative error (linearity)	<2%	<0.5%

Table 1. Requirements for load cell (sensor for measuring the contact force)

The foil sensor for measuring the contact pressure (normal stress within the contact area) must allow for continuous (pressure over time) or peak measurement (maximum pressure only). It must made of a flexible material that enables the foil to withstand the deformations of the damping material during the test. The foil sensor must fulfill the following requirements:

	Minimum	Recommended
Calibrated range	500 N/cm^2	750 N/cm^2
Density (sensor cell per area)	4 cm^{-2}	16 cm^{-2}
Relative error (linearity)	<20%	<10%

Table 2. Requirements for foil sensor (sensor for measuring the pressure within the contact area)

Note 1: It may be necessary to equilibrate and calibrate the foil sensor before using it. This protocol does not give any guidelines to prepare the foil sensor for the measurement, since the procedure depends significantly on the foil's specifics and measurement principle. Refer to the documentation (datasheet or manual) of the manufacturer.

Note 2: Some foil sensors allow for adjusting the measurement sensitivity. Use always the highest possible sensitivity so that the result is still within the measurement range. The sensitivity is too high if the signal of at least one measurement cell of the foil saturates.

Note 3: Assure that the dimensions of the foil sensor are slightly larger than the actual contact area.

Use the form in Annex B to report the capabilities of both sensors used for the validation.

Example: Sensors

Feature	Force Sensor	Pressure Sensor
Manufacturer and type	Sensor Company, PE 1000	Sensor Company, Foil 750
Calibrated range	1000 N	750 N/cm^2
Miscellaneous	Number of axes: 1	Density: 20 cm^{-2}

4.2 Method

The load-cell must be part of an instrument that mimics the biomechanical characteristics of the human body or at least of the endangered body parts. Figure 2 depicts the general design of such a device. It consists of an impactor attached to a changeable spring. The spring typically simulates the stiffness of the bone. Linear guides ensure that the impactor can move only into the active direction of the spring. The spring is further attached to a load-cell that is rigidly connected to the housing of the instrument. A soft damping material covers the top side of the impactor. This part simulates the stiffness that stems from the soft tissue on the body part. The combination of damping material and spring must realize the same biomechanical characteristics as the considered part of the human body has. The foil sensor for pressure measurement is on the top of the damping material.

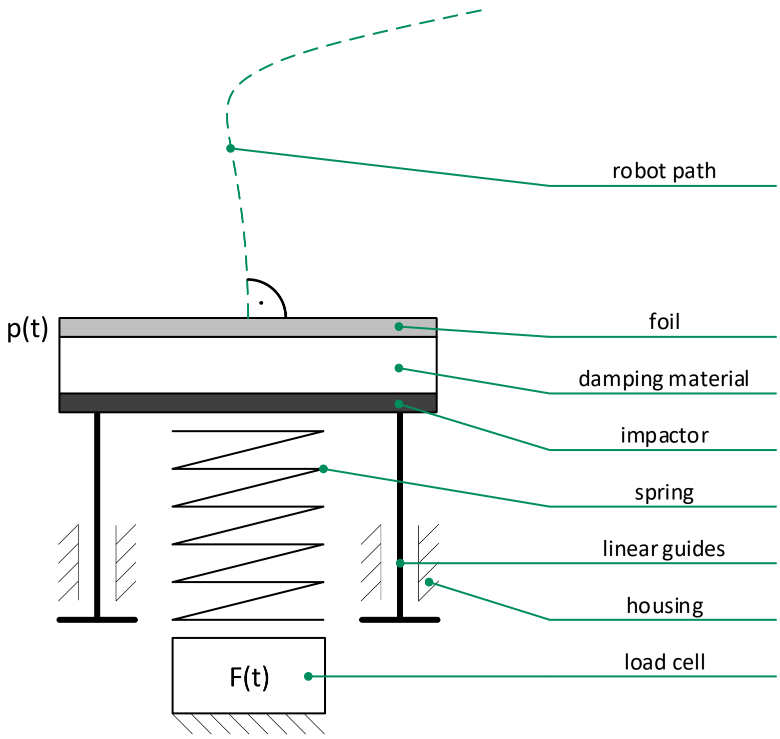

Figure 2: General structure of the collision instrument

Essentials for data acquisition are:

- A computer for measurement control
- All devices and software (running on the computer) necessary to control the sensing devices and to record their signals (incl. data logger, charge amplifier, etc.)

Note: The manufacturers of the commercially available measurement systems usually provide software to control their devices and to analyze the results. Please ensure that you have access to such software, especially for your instruments. If there are separate tools for force and pressure measuring, run both tools in parallel.

Data acquisition for all signals (force and pressure) must comply with the following requirements:

	Minimum	**Recommended**
Sampling frequency	2’000 Hz	10’000 Hz
ADC resolution	12 bit	16 bit
Time to contact	2 s	5 s

Table 3. Requirements for data acquisition

Note: Ensure that the sensor’s bandwidth enables the instruments to sample the signals with the envisaged sampling frequency.

Time to contact denotes the time the measurement instrument start the recording of the signal before initial contact. If a sensor for test does not fulfill the minimum requirements, configure the properties at the best possible values (e.g. highest sampling rate). Please record the applied configuration using the form in Annex B.

Example: Acquisition Configuration

Feature	Force Sensor	Pressure Sensor
Sampling frequency	10.000 Hz	1.800 Hz
ADC resolution	16 bit	8 bit
Time to contact	10 s	10 s

5 Procedure

5.1 Test Plan

The test plan is a summary of all situations the risk assessment identified as hazardous due to possible physical contact between the exoskeleton and a bystander, incl. all combinations of applicable conditions. Therefore, the test plan provides a detailed summary of which tests are necessary to validate the skill for the considered application.

The protocol user must test each impact identified by the risk assessment as potentially hazardous (see Section 2.1). The tests simulate the impacts the exoskeleton may cause, whereby the measurement instrument introduced above represents the body part of the endangered human (see Section 4.1 and 4.2). The objective of the test is to prove whether the contact forces and pressure exceed the metrics or not (see Section 2.2).

According to Chapter **Error! Reference source not found.**, the protocol must consider the following conditions:

- Robot system
  - Exoskeleton speed
  - Exoskeleton load
  - Segment length
  - Segment surface / mounted devices
- Sub-system
  - Not available
- Environment
  - No obstacles
- Miscellaneous
  - Location and shape of the contact area on the exoskeleton
  - Endangered body parts

For the validation test, it is necessary to measure all possible combinations of conditions that apply to the considered hazardous situation. Each combination corresponds to a particular test case. It is recommended to organize all hazardous situations and applicable conditions row-wise in a list. Each row in the list represents a particular test case that the protocol user must execute and report on using the form in Annex B. The protocol user should repeat each test three times.

5.2 Preparation

5.2.1 Test Arrangement

The setup includes all devices that are required to validate the robot system. Please go through the following subsection to prepare the setup properly:

Exoskeleton system

- If the exoskeleton under validation is an overground or ambulatory exoskeleton (i.e. it can move in the room and is not part of a stationary training device), attach it to a fixed frame (see fig. 3 fixation of exoskeleton).

Measurement Equipment

- Connect all sensors to their loggers and the loggers to your computer.
- Configure the parameter of the data acquisition within the range specified in Section **Error! Reference source not found.**.
- Make sure that you can start and stop the recording of all signals from your computer and that the acquisition works as configured.

Bio-fidelic measurement Instrument

- Install the spring and apply the damping material to the impactor (see test plan). Make sure that the characteristics of the used combination fit the stiffness of the endangered body part (see Section 3.3).
- For each test, attach the collision instrument to a stiff frame that holds it in place during the test and avoids significant deformations when subjected to the expected forces. For instance, use aluminum profiles to create an appropriate support structure.
- For each test, assure that the contact point on the robot surface strikes perpendicular on the impactor of the measurement instrument in the moment of initial contact (**Error! Reference source not found.**).

Pressure Sensor

- To avoid damage to the pressure foil, cover it with a PTFE foil (thickness <50 µm).
- Rough surfaces can result in small regions of significant peak pressures. To avoid them, use a microfiber cloth (thickness <500 µm).
- Make sure that the sensitive area of the foil covers the contact area completely.
- Use rubber bands or tape as fasteners to attach the foil to the impactor of the collision instrument. Ensure that the fastener does not run over the sensitive area of the pressure foil.

⚠	**Warning**
	The applied combination of spring and damping material must simulate the response behavior of the body part to be tested. In order to select the right combination, it may also be necessary to consider the shape of the contact area on the robot surface.

⚠	**Warning**
	The stiffness of the instrument support must be 20x higher than the stiffest spring used for all tests.

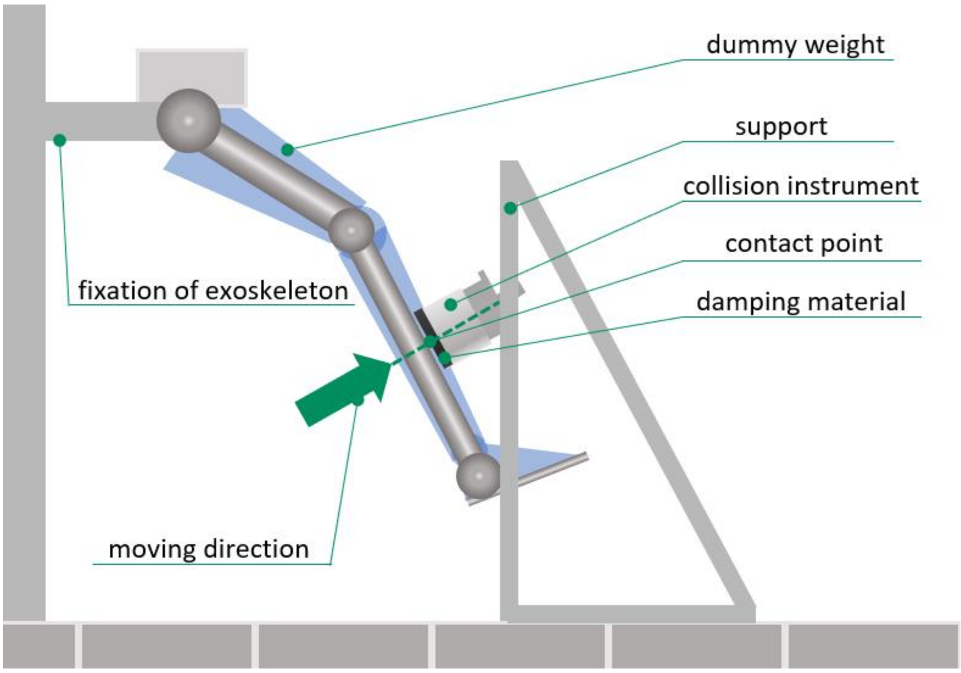

Figure 3: Schematic drawing of the setup

Use the form in Annex B to record the applied spring and damping material:

Example: Configuration of the Collision Instrument

Spring rate (N/mm)	120
Hardness of damping material	40 (Shore hardness)

5.2.2 System Conditions

The protocol user must configure the exoskeleton in exactly as it will run in the intended application that includes at least the following steps:

- Switch on the exoskeleton one hour before beginning the tests (warm-up phase).
- Add dummy weights to the exoskeleton to mimic the real use situation with a patient/exoskeleton user in the system. The segment weights and their center of mass should represent the anthropometric values of the human and relate to the maximum user weight and height as specified by the manufacturer.
- Install/select the training program to be tested. Note that the test has to be executed for each training program separately. In the event one test applies for multiple training programs, explain in a rationale why.
- Configure all available safety-functions.

⚠	**Warning**
	The safety configuration, and so the safety skill, is often a part of the robot program or inseparably connected with it. Therefore, the protocol user must not change the robot program after passing the validation successfully. It is highly recommended to store a backup of the positively tested program and to lock the robot control unit so

	that only authorized people can modify the program or the safety configuration. Any modification to the program may require a new validation of the safety skill.

Note: If the robot has no safety functions to limit the interaction energy, the protocol user must test the worst-case scenario, in which the robot moves at maximum speed, even if this speed is not required for the intended application.

5.2.3 Environmental Conditions

The environmental conditions should reflect the normal environment in which the exoskeleton will be used. If environmental conditions such as lighting, temperature or humidity affect the safety skill, perform the test in the worst-case combination of such conditions.

Depending on the risk assessment, perform the test in one or both of the following conditions.

- No obstacles (endangered part of the human body is spatially unconstrained and can move freely following the direction of the contact force)
- Obstacles (endangered part of the human body is spatially constrained and cannot move freely into the direction of the contact form)

5.3 Test Execution

Apply the following steps for each test case:

- Move the exoskeleton segment slowly to the point where the impact can occur (see test plan or risk assessment).
- Check if the measuring instrument is in the right position and orientation. It is in the right position if the exoskeleton almost touches the instrument's impactor when reaching the contact point along the path. It is in the right orientation if the moving direction of the contact point is perpendicular to the impactor plate (see Section **Error! Reference source not found.**).
- Move the robot backward to a starting position from which the robot has enough time to accelerate to its programmed speed before reaching the contact point.
- Take a photo of the test situation (recommended).
- Start the measurement instruments.
- Start the robot movement.
- After the robot hit the collision instrument and stopped, take another photo of the situation (recommended).
- Save the recorded signals.
- Release the robot by moving it under manual control backwards.
- Rearrange the pressure foil and damping material on the impactor (if it slipped during the collision) and repeat the tests at least twice (see Section **Error! Reference source not found.**).

5.4 Data Processing and Analysis

After finishing the last repeat, there should be three results available. It is recommended to start by filtering each signal right after recording. Since the pressure signal is technically a sequence of images (for pressure measurement over time) or a single measurement (for measuring only the peak pressure), it might be necessary to apply an additional image filter that reduces the image noise. The requirements for both filter types are:

Signal Filter (for all signals)	Minimum	Recommended

Signal filter type	1st order Butterworth low pass	4th order Butterworth low pass, zero-phase
Cut-off frequency	200 Hz	200 Hz
Image Filter (for pressure only)	**Minimum**	**Recommended**
Image filter type	(no filtering)	Gaussian filter
Standard deviation	N/A	$\sqrt{2/\pi}$

Table 4. Requirements for signal and image filtering

For image filtering, it is highly recommended to use a software that has filter techniques included. In general, the manufacturers of the pressure measurement system provide such tools in combination with the sensor. Use the form in Annex B to record the applied filter configuration.

Example: Signal Filter Configuration

	Force Sensor	**Pressure Sensor**
Signal filter type	4th order Butterworth low pass, zero-phase	4th order Butterworth low pass, zero-phase
Cut-off frequency	200 Hz	200 Hz
Image filter type		Gaussian filter
Standard deviation		$\sqrt{2/\pi}$

Once the signal were filter, signals offsets must be compensated by subtracting the average magnitude the signal has in the period from 0.5 s to 1.5 s (0 s marks start of signal recording). Figure 4 illustrates the procedure for the force signal.

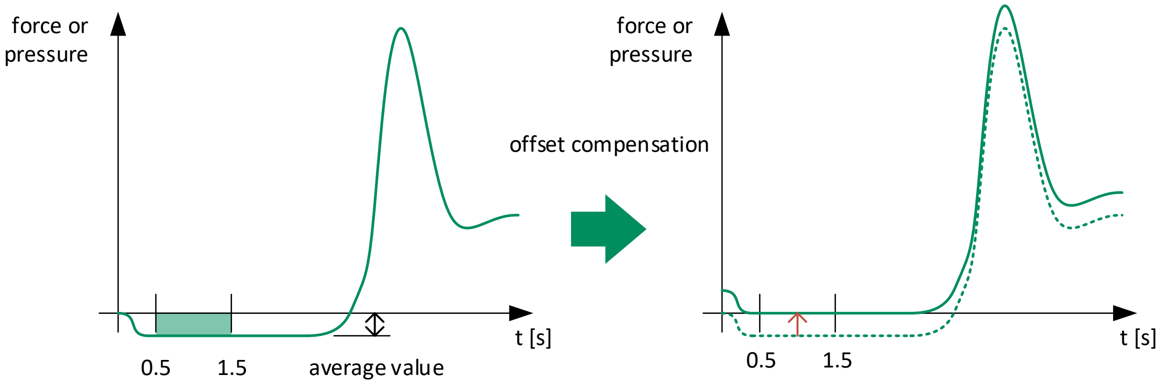

Figure 4. Procedure for Offset Compensation

Determine the maximum contact force and peak pressure for the transient and quasi-static contact phase. Ensure that the maximum values for the transient phase were determined within the time window from 0 s to 0.5 s and the ones for the quasi-static phase after 0.5 s, while 0 s marks the start of the contact (see Figure 5).

Note: In the event the pressure foil measures only the peak pressure, it is necessary to use the maximum value for both contact phases.

In a free collision, the affected body part is spatially unconstrained and thus can move freely. However, the proper use of the measurement instrument requires to mount it on a solid support frame, why it cannot simulate the dynamics of a free collision. This inability must be compensated with the following methodology that converts the maximum forces and pressures measured under constrained conditions into values that resemble the results of measurements under unconstrained conditions.

Determine the time T at which the maximum transient contact force appears. Estimate the effective mass m_R of the exoskeleton with the following expression

$$m_R = \frac{2}{\pi} \frac{T}{v_R} F_{TR} \quad ,$$

where v_R is the collision speed and F_{TR} the maximum force measured in the transient phase. If v_R is unknown, use the velocity limit as set in the safety configuration. In case the robot has no safety-rated velocity limitation, use the maximum possible velocity the robot can reach. Use the m_R to calculate the factor

$$R = \sqrt{\frac{1}{1 + \frac{m_R}{m_H}}} \quad .$$

The parameter m_H is the effective mass of the body part that belongs to the bystander affected by the collision. If this mass is unknown, please take the correct value from Table 5. Ensure that all values in SI based units (mass in [kg], force in [N], time in [s], and velocity in [m/s]).

Round the factor R to the first digit after the comma and multiply it to the maximum force F_{TR} and maximum pressure p_{TR} measured in the transient force under constrained spatial conditions. As the reduction factor R is always lower than one $R < 1$, it will lead to lower maximum forces and pressure that correspond to the values, which the test would have obtained under unconstrained spatial conditions.

Affected Body Parts	m_H **(kg)**
Head	10
Neck, trunk, upper extremity (upper and lower arm)	50
Hand	5
Lower extremities	90

Table 5. Effective masses of human body parts

Record the maximum contact forces and pressures for both the transient phase and the quasi-static phase, the time T to the maximum force, the calculated reduction factor R, and all other values factored in.

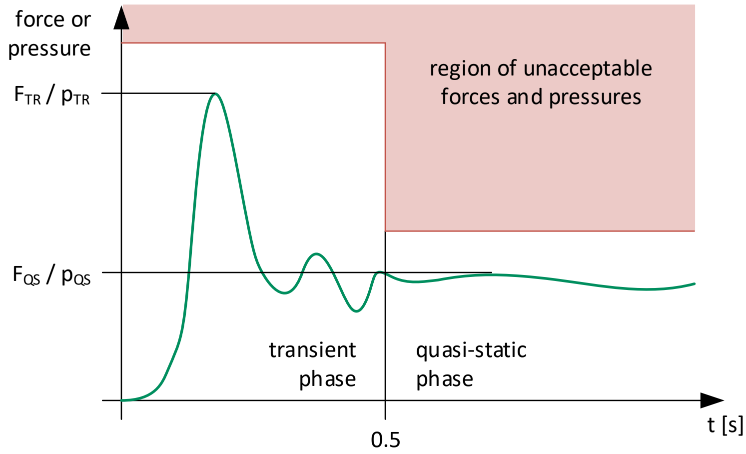

Figure 5. Illustration of the transient and quasi-static force, including regions of acceptable forces / pressures

	Suggestion
	To minimize the efforts for the pressure measurement, it is recommended to begin with force measurement only. If the maximum contact force is significantly below the applicable limit value, repeat the test three times including pressure measurement. If the maximum force of the first test already exceeds the force limit, the protocol user can omit pressure measurement for this test.

Example: Result from Data Analysis

Reduction factor to convert measurement values				
Effective human mass (kg)	50	50	50	
Maximum force* (N)	313	301	330	
Time to maximum* (s)	0.23	0.21	0.24	
Robot speed* (m/s)	0.5	0.5	0.5	
Effective Robot Mass (kg)	92	81	101	
Reduction factor	0.59	0.62	0.58	
*) only required if the effective robot mass is unknown				
Measured maximum values	**Test 1**	**Test 2**	**Test 3**	**MAX**
Transient contact phase				
Maximum force (N)	313	301	330	330
Maximum pressure (N/cm²)	54	59	61	61
Reduced force (N)	185	187	191	191
Reduced pressure (N/cm²)	32	37	35	37
Quasi-static contact phase				
Maximum force (N)	159	145	165	165
Maximum pressure (N/cm²)	34	39	41	41

If the highest maximum of all force and pressure values exceeds the applicable limit value, the safety skill fails the test. It is then recommended to modify the robot program (for instance by reducing the speed) and to start over with the validation process. Other options could be a modification of the safety configuration or conditions. If the highest maximum does not exceed the limit, the robot passes the test.

5.5 Report

Use the form in Annex B 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 able to mitigate the risk effectively and to protect the robot operator. Use the last section in the form to record the overall result of the test (passed/failed).

Example: Summary

	Test 1	**Test 2**	**Test 3**	**Tests Passed**
Passed transient phase	yes	yes	Yes	yes
Passed quasi-static phase	yes	yes	no	no
Passed both phases	yes	yes	no	no

6 Annexes

A Stiffness Parameter of the Human Body

See Table 6 to find the right combination of damping material and spring for the body part you want to test with your bio-fidelic measurement instrument

Note 1: You can neglect Table 6 if you have other data available for configuring the spring-damping characteristics of your bio-fidelic measurement instrument. Nevertheless, record the source of your data in the record forms.

Note 2: Data given in Table 6 are subject to modifications.

Table 6. Combinations of damping material and spring to mimic the biomechanical characteristics for various body regions (source: DGUV FBHM 080)

<table>
<tr><th>Body region</th><th>Hardness
(shore A)</th><th>Thickness
(mm)</th><th>Spring
(N/mm)</th></tr>
<tr><td>Skull and Forehead</td><td rowspan="7">70</td><td rowspan="7">7</td><td>150</td></tr>
<tr><td>Face</td><td>75</td></tr>
<tr><td>Hand and Finger</td><td>75</td></tr>
<tr><td>Neck</td><td>50</td></tr>
<tr><td>Forearm and Wrist</td><td>40</td></tr>
<tr><td>Chest</td><td>25</td></tr>
<tr><td>Pelvis</td><td>25</td></tr>
<tr><td>Lower Leg</td><td rowspan="4">30</td><td rowspan="4">14</td><td>60</td></tr>
<tr><td>Upper Leg and Knee</td><td>50</td></tr>
<tr><td>Back and Shoulder</td><td>35</td></tr>
<tr><td>Upper Arm and Elbow</td><td>30</td></tr>
<tr><td>Belly</td><td>10</td><td>21</td><td>10</td></tr>
</table>

B Report Form

Use the form on the next page to record the data for each test.

Test ID / Test no	
Hazard ID	
Description	
Photo	

Setup

Sensors

Feature	**Force Sensor**	**Pressure Sensor**
Manufacturer and type		
Calibrated range		
Miscellaneous		

Acquisition Configuration

Feature	**Force Sensor**	**Pressure Sensor**
Sampling frequency		
ADC resolution		

System Configuration

Exoskeleton	
Manufacturer	
Model	
System Configuration	
Control Software	
Fixation (for mobile exoskeletons)	
Manufacturer	
Model	
Description	
Mounted optional constructions	
Manufacturer	
Model / Type	
Description	

Safety Skill Properties (can be test-specific)

Test Specifics

System State

Configuration Space	A1	A2	A3	A4	A5	A6	A7
Axes position (deg)							
Axes velocities (deg/s)							
Workspace	**ABS**	**X**	**Y**	**Z**			
Segment velocity (mm/s)							
Override (%)							

Misc. Conditions

Contact Area (on exoskeleton structure)	
Location	
Photo	

Endangered Body Part and Limit Values

Body Part	Force (N)		Pressure (N/cm²)		Stiffness (N/mm)
	TR	QS	TR	QS	
Forearm muscle					
Source					

Configuration of the Collision Instrument

Spring rate (N/mm)	
Hardness of damping material	

Test Result

Result from Data Analysis

Reduction factor to convert measurement value				
Effective human mass (kg)				
Maximum force* (N)				
Time to maximum* (s)				
Robot speed* (m/s)				
Effective Robot Mass (kg)				
Reduction factor				
*) only required if the effective robot mass is unknown				

Measured maximum values	**Test 1**	**Test 2**	**Test 3**	**MAX**
Transient phase				
Maximum force (N)				
Maximum pressure (N/cm^2)				
Reduced force (N)				
Reduced pressure (N/cm^2)				
Quasi-static phase				
Maximum force (N)				
Maximum pressure (N/cm^2)				

Summary

	Test 1	**Test 2**	**Test 3**	**Tests Passed**
Passed transient phase				
Passed quasi-static phase				
Passed both phases				