Being safe around collaborative and versatile robots in shared spaces

Protocol

Test Limit Restraining Energy for lower limb Exoskeletons

(EXO-LRE-1)

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

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!

Disclaimer: This protocol reflects the current and collectively developed state of the art in the validation of a specific safety skill for a collaborative robot. However, you may have to adapt the described validation procedure to be feasible for your particular application, circumstances and applicable regulations. Neither the COVR project consortium as a whole nor any individual partner of the consortium takes, therefore, any responsibility for the correctness and completeness of the validation procedure described here.

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CONTENTS

1 Introduction

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

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

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

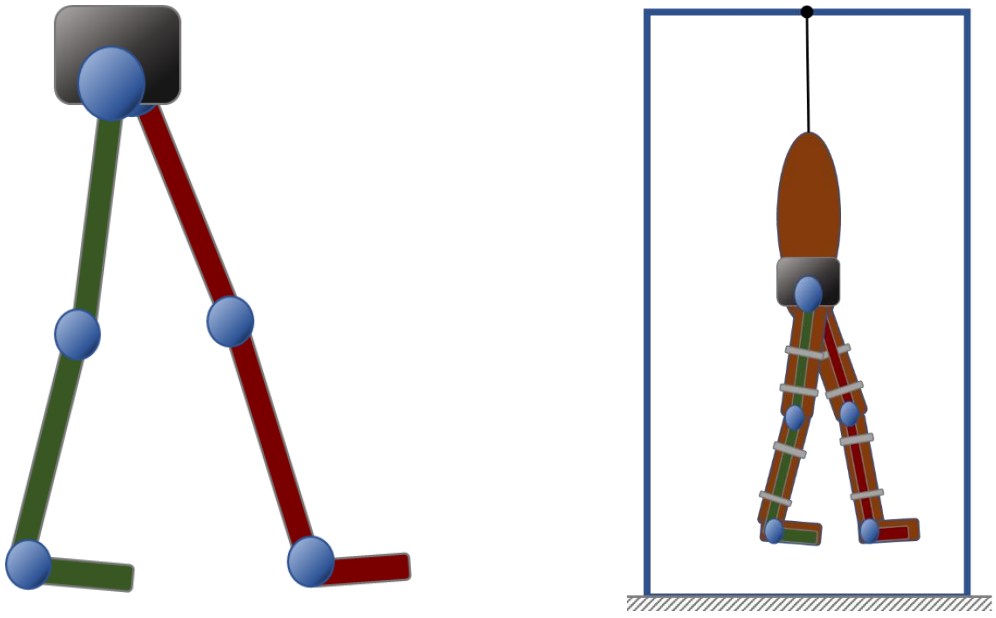

Figure 1: Exemplary application featuring situation

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	Limit Restraining Energy
System	Lower limb Exoskeleton
Domain	Healthcare, Industry, Logistics
Conditions	Indoor, even terrain, uneven terrain
Measurement Device(s)	(passive) Instrumented limb

⚠	**Warning**
	This protocol supports users only to validate the effectiveness of the skill listed in the profile above. The skill should be a technical measure for the robot system to mitigate

	the risk of one potentially hazardous situation as identified in the mandatory risk assessment. Consequently, the risk assessment must be done before using this protocol.

1.2 Definitions and Terms

Exoskeleton (SOURCE: ASTM F3332-20)

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

Exoskeleton system (SOURCE: ASTM F3323-20)

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

Instrumented limb (source: local to this document)

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

Mirror limb (source: local to this document)

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

Monocentric joint (source: ISO 13405-2 – clause 6.3.3)

The axis of rotation is constant for all angles of flexion.

Polycentric joint (source: ISO 13405-2 – clause 6.3.3)

The axis of rotation changes with the angle of flexion.

RACA robot (source: EN-IEC 80601-2-78:2020 – clause 201.3.212)

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

Rehabilitation robot (source: local to this document)

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 a restraining type RACA robot* applies forces to (parts of) a human limb. For the intended use of this kind of RACA robot*, a transfer of forces is usually required

to achieve the desired effect. The magnitude of force transmission is directly related to safety. However, little literature is available concerning force limits based on experiments with humans.

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

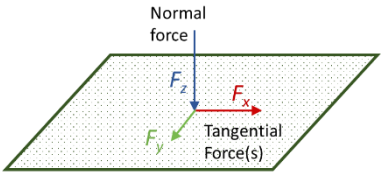

Figure 2 Force components

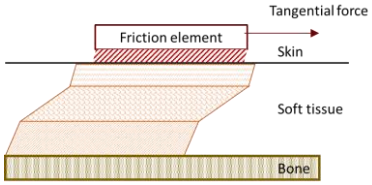

Figure 3 stress effect tangential force

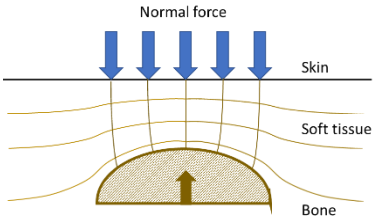

Figure 4 stress effect normal force

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

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

2.2 Target Behavior and Metrics of the Safety Skill

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 Conditions

In case the conditions under which the hazardous situation may occur can change, the user of this protocol shall develop a test plan containing all their reasonable and relevant combinations. The user must test the applied skill for each combination of this list. Therefore, it is important to know the conditions with the most significant influence on the target metrics. Please report all conditions, represented by values, for each test using the form in Annex A.

3.1 System

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

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

The tests should therefore be performed:

- Under the specified maximum normal use speed v [m/sec] or [deg/sec]
- Reaching the specified maximum flexion angle α [deg] during normal use.
- Under the specified load conditions that are representative for normal use.
- With an active RACA robot* and a completely passive instrumented limb*
- When relevant, also with an active RACA robot* and a (partially) active instrumented limb*[1]

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

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

When relevant, mounting or placement of the RACA robot* for the tests should be in such a manner that it represents as close as possible a normal situation. This is especially relevant for lower limb restrain type RACA robots*, like lower limb exoskeletons, where in certain situations the limb needs to support (part of) the weight of the subject.

3.2 Environment

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

Conditions that may influence the safety skill may be:

- Floor surface (e.g. level floor, uneven floor, ramps, etc.)

3.3 Miscellaneous

N.A.

4 Test setup

4.1 Equipment

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

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

The instrumented limb* consists of:

- at least a single joint that mimics the behavior of the corresponding human joint – but preferably mimics the entire limb.
- force sensors to measure the 3D net forces in separate interaction areas on the limb.
- sensors to measure the angle between the segments
- segments that mimic the shape of a human limb
- A cover material that mimics the properties of human skin and underlying soft tissues as described in annex B of ISO TR 23482-1:2020

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

Preferably the instrumented limb* is attached to a dummy trunk via a joint that mimics the passive behavior of the hip joint. The attachment of the instrumented limb* to the dummy trunk should mimic the pelvic and lumbar region so the lower limb exoskeleton can be attached to the dummy as would be in a normal use case.

The weight of the mannequin should match that of the intended use population. According to IEC 60601-1 for adults the weight is set at 135 kg plus 15 kg for accessories. When the system is intended to be used by children a lower weight can be used. The weight used in the tests should be reported in the test form (Annex A). The weights of the segments of the instrumented limb* should match the normal segments weights in a subject with the defined weight.

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

4.2 Method

The instrumented limb*, used to measure interaction forces with an exoskeleton, is mounted to a mannequin trunk via a passive 3D hip joint. A second, non-instrumented, limb (mirror limb*) is mounted with an identical passive 3D hip joint to the mannequin, so the mannequin is symmetric and allows for experiments with bilateral lower limb exoskeletons.

The trunk of the mannequin is tilted forward under an angle between 0 and 5 degrees, to mimic normal posture of an exoskeleton user.

The whole setup of mannequin trunk, instrumented limb* and mirror limb* is attached to a winch, which is mounted to a stable frame that allows the entire setup to be lifted and lowered as required before and after the tests.

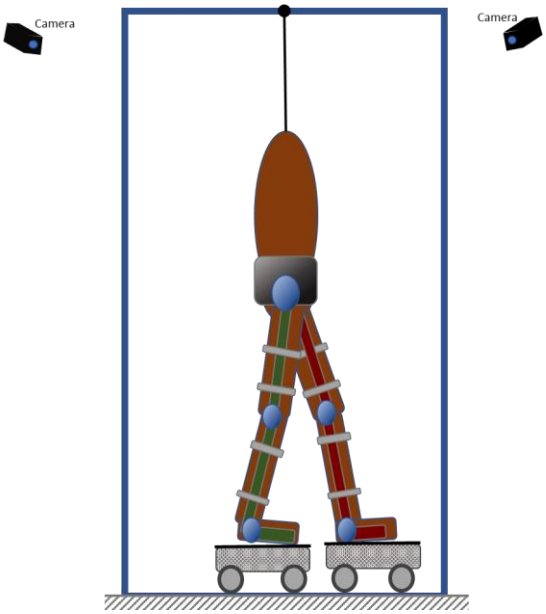

Figure 5: General structure of an appropriate test arrangement with a instrumented limb (e.g. Exosafe Leg-Replica)*

For each foot of the exoskeleton, a structure is positioned that can move in the anterior/posterior (AP) direction. For each of the feet, a "floor plate" will move with the AP position of the individual foot. This plate will maintain a constant vertical height to mimic a floor during normal gait, thus avoiding contact with the exoskeleton foot during the swing phase for that limb. Optionally, the "floor plate" can be covered by specific materials to test the effects due to different floor materials.

These artificial "floor plates" will be controlled based on the movements of the limbs of the exoskeleton. These movements will be tracked in real-time via a 3D motion capture system, where reference points will be available on the frame with the moving floor plates and tracking point on the feet of the exoskeleton.

Up and down movements of the dummy during the normal use situation are fully passive, but guided by a low-friction vertical guide system.

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

4.2.1 Data Acquisition

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

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

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

5 Procedure

5.1 Test Plan

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

The test plan should contain a description of the motion pattern/gait pattern used during the test. This pattern should describe ROM*-ranges for the actuated joints of the exoskeleton and timing of the movements of the exoskeleton. This description or a reference to a detailed description should be reported in the test form of Annex A.

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

- Robot system
  - The mannequin (including the instrumented limb* and the mirror limb*) should have a weight that corresponds with the max weight allowed for the exoskeleton, as defined by the manufacturer. The weight should be recorded in the test form (Annex 0).
  - The motion pattern/trajectory for the RACA robot* needs to be defined and (a reference to) a description should be reported in the test form (Annex A)
- Environment
  - Testing should be performed using an “even floor” emulation
  - Uneven floor situations may also be considered.
- Miscellaneous
  - N.A.

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

5.2 Preparation

Before executing a particular test from the test plan, it is necessary to prepare the setup and the conditions properly. The following sections gives instruction to prepare each part of the setup and all conditions with a significant influence on the target metrics.

5.2.1 Test arrangement

- The testing frame setup, instrumented limb and motion capture system are prepare according to their manuals.
- The motion capture system is calibrated
- The mannequin trunk is attached to the winch in the suspension frame and lifted to the working height.
- The instrumented limb* and the mirror limb* are fixed to an aluminum profile symmetrical to the mannequin center at the (approximate) location of the hip joint centers of the mannequin. The mannequin is lowered with the winch until the profile matches with the hip joint of the exoskeleton.

- The exoskeleton is fixed to the trunk of the mannequin, the instrumented limb* and the mirror limb* according to the manual (i.e. in the same way it should be fixed to the human body for normal use).
- (IF NEEDED) The exoskeleton is tied to the horizontal bar of the structure to prevent high slips of the device that could prevent the test to finish. When needed, a note of this in the test form (Annex 0) should be made.
- The mannequin + exoskeleton setup is lifted from the ground by actuating the winch.
- The exoskeleton frames are adjusted according to the desired alignments at the knee and ankle level.
- With the same frame configuration, also the right frame is adjusted on the mirror limb*.
- Markers for the motion capture system are placed:
    - on defined positions of the testing frame setup, from which the location and direction of the "floorplates" are well defined.
    - the feet of the exoskeleton:
        - HEE : back of the heel
        - TOE : front of the foot
    - the knees of the exoskeleton:
        - KNE : at knee joint of the exoskeleton, at height of the knee joint of the instrumented limb*
    - The hip joints of the exoskeleton:
        - HIP : at hip joint of the exoskeleton, at height of the hip joint of the instrumented limb*
- The hip and knee joint of the instrumented limb* are measured relative to the horizontal bar in the mannequin (**Error! Reference source not found.**). The vertical hip and knee joint center coordinates of the instrumented limb* are taken as constant parameters of the test.
- Connections for communication, and optional trigger are connected to the exoskeleton.
- The battery of the exoskeleton is connected.
- The power supply and communication connection are connected to the instrumented limb*.

5.2.2 Environmental Conditions

For uneven surface tests, the floor plates can be covered with a surface material to mimic an uneven floor surface

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

5.2.3 System Conditions

- If needed, a soft tissue material, as specified in ISO TR 23485-2:2020, should be placed under each cuff. The use of a soft tissue simulating material should be noted in the test form
- The tests should be executed under normal use conditions as well as for those S.F.C.'s* that may have an impact on the implemented safety skill. The test condition should be noted in the test form (Annex 0).

5.3 Test Execution

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

- The exoskeleton straps are adjusted on the instrumented limb* and the mirror limb* according to the preferred configuration of cuff position and tightening level
- Start the data acquisition for the motion capture system and the real time control of the floor plates
- Place lower the exoskeleton (and mannequin) onto the floor plates, so the weight of the exoskeleton and mannequin are supported by the floor plates
- The exoskeleton is controlled to reach its initial position (all the limbs aligned with the exoskeleton in standing position)
- The possible initial (translational) misalignment of the exoskeleton's joints relative to the joint of the instrumented limb* is measured. The same vertical reference used in step 4 of the preparation procedure is taken. The difference between this measure and the joint position of the instrumented limb* is the initial misalignment of each joint. Note these values in the test form (Annex 0).
- Data acquisition is started for the instrumented limb*.
- The program controlling the exoskeleton is launched.
- The exoskeleton is started to generate the required gait pattern.
- The gait pattern is kept running for at least 3 minutes with the following joint range of motion (except if another pattern has been defined in the test plan):

  Hip joint gait ROM: [-15,30] deg

  Knee joint gait ROM: [0,60] deg

  Ankle joint gait ROM: [-14, 20] deg

- The exoskeleton stops the gait pattern after the desired time.
- Data acquisition is stopped for the instrumented limb*.
- Stop the data acquisition for the motion capture system and the real time control of the floor plates
- The possible final misalignment of the exoskeleton joints relative to the joint of the instrumented limb* is measured (again with the same vertical reference used in step 4 of the preparation procedure) and recorded in the test form (Annex 0).

5.4 Data Analysis

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

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

5.5 Report

Use the form in Annex 0 to report all conditions and results of the tests. After finishing the validation successfully (all tests passed), add the forms to your risk assessment. They are proof that the applied safety skill is active and gives the expected protection to the robot operator working beside the collaborative robot.

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

6 Bibliography

EN-IEC 60601-1:2006

EN-IEC 80601-2-78:2020

ISO TR 23482-1:2020

Annex A - Test form

Limit restraining energy for Exoskeleton

Test form - Protocol EXO-LRE-1			
Test date		**Name of tester:**	
Test ID		**Hazard ID**	
Picture of test setup			
System and System conditions			
Description of RACA robot* under validation			
Type RACA robot*		**SN**	
Motion pattern used (reference or description)			

	Height	**Anterior/posterior**
Initial misalignment hip instrumented limb		
Load used		
Velocity		
Inclination		
Control mode RACA robot*	Full control / Co-control	

Connection areas:	**Location**	**Limit max force**	**Limit average force**
A[2]			
B			
C			
D			
E			
F			
G			
H			
…			
Picture of test setup with-numbering of connection areas			

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

Conditions: Enviromental			
Floor surface			

Conditions: Miscellaneous			

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

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

Test results

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

Summary EXO-LRE-1 tests

Date of testing	
Name of tester	
Overall conclusion	
Signature	