Being safe around collaborative and versatile robots in shared spaces

Protocol

Test Prevention of Spatial Overreaching for the Subject (Robot in Control)

ROB-LRM-2

The purpose of this protocol is to validate the safety skill "limit range of movement" for rehabilitation robots, where a limb of a subject has a connection point with the robot (either free or restrained) and the robot can move that point within a 3D volume. The range of motion is assessed using opto-electronic 3D marker tracking.

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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National Research Council of Italy
Roessingh Research and Development

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1 Introduction

The purpose of this protocol is to validate the safety skill “limiting a range of movement” in 3D of a RACA* robot by restricting spatial range of motion for both its end-effector as well as any other part of the RACA* robot, in order to avoid physical damage to the patient connected to this RACA* robot.

The primary hazardous situation considered here is an over stretching of the subject/user limbs, where the distance between a proximal and a distal joint is too large.A secondary hazardous situation considered in this protocol, is that parts of a robotic arm type RACA* robot may collide with parts of the body or the subject.

1.1 Scope and limitation

This protocol is specifically limited to the following profile:

Skill	limit range of movement
System	robotic arm (stationary RACA robot)
Sub-System	mounting platform for the robot arm that stabilizes the position of the robot are relative to the body of the subject.
Domain	cross-domain
Conditions	3D movement Robot controlled driven (so “no” human control on movement – for the subject it is a passive motion)
Measurement Device(s)	Optoelectronic measurement system / motion tracking system
Out of scope	This protocol does not apply for robots where the subject is in control or in co-control. For that situation this protocol applies. This protocol does not apply to collaborative robot applications in other domains than rehabilitation.

⚠	**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

Active movement (source: local to the document)

A movement of parts of a human body, produced by muscles of that human

Direct path (source: local to the document)

A movement trajectory between two points, where the path is depending on robot path planning (can be linear in space or not if interpolation is done on joint coordinate)

End effector (source: ISO 8373)

Device specifically designed for attachment to the mechanical interface to enable the robot to perform its task

Monitored point (source: local to the document)

Either a point on the robot or defined as a point in space in relation to a specific point on the robot. For example, if the monitored point is to be represented by the subjects' hand, it might be defined as a point in a fixed distance from the arm splint.

Marker (source: local to the document)

Active or passive spatial element used by an optoelectronic measurement system to determine a spatial position within a predefined volume.

Motion tracking system (source: local to the document)

A system used to detect spatial coordinates of objects in a restricted volume as a function of time

Optoelectronic measurement system (source: local to the document)

A system used to detect spatial coordinates of objects in a restricted volume by camera like sensors.

Overreaching (source: local to the document)

A movement that results in the monitored point* exceeding the range of motion. Can be harmful to the subject as the movement can exert an excessive strain on joints.

Passive movement (source: local to the document)

A movement resulting from an external force working on parts of a human body (e.g. limb), without any voluntary contribution to that motion by that human.

Predefined path (source: local to the document)

A movement trajectory that is specified with more parameters, possibly a set of spatial coordinates.

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

Medical robot intended to perform Rehabilitation, Assessment, Compensation and Alleviation robot, comprising an actuated applied part

Range of Motion (ROM) (source: local to the document)

A combination of linear and angular distance that a defined monitored point* may move in relation to a defined reference point. The monitored point* can be either a point on the robot, or a point on the body of a human subject defined relatively to a point on the robot. The ROM can be limited to a straight line (one-dimensional ROM), a plane (two-dimensional ROM) or a space (three-dimensional ROM) in any shape. Has to be defined in relation to a reference point.

Reference point (source: local to the document)

Either a point on the robot or defined as a point in space in relation to a specific point on the robot. For example, if the reference point shall represent the expected location of the subjects' shoulder joint center, it might be set at a fixed distance from the robot surface. Please note that the reference point has to be a spatial location, which keeps a known position in relation to proximal parts of the robot.

Rehabilitation robot

See RACA robot

S.F.C. / **Single fault condition** (source: 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

Target point (source: local to the document)

Location of a point in a certain volume, relative to the reference point, the robot will be instructed to move the monitored point* to.

2 Concept and Objectives

2.1 Hazardous Situations

During rehabilitation, a patient will be attached to the robot, in order to mobilize a limb. Therefore the robot will actively move the attached body part. Based on anthropometric properties and physical restraints of the subject as well as the required movement types, the therapist will set some specific boundaries to the movements of the robot arm, in order to make sure the distance between a proximal joint center (e.g. shoulder or hip) and a distal joint center (e.g. wrist or ankle) stays within a certain area.

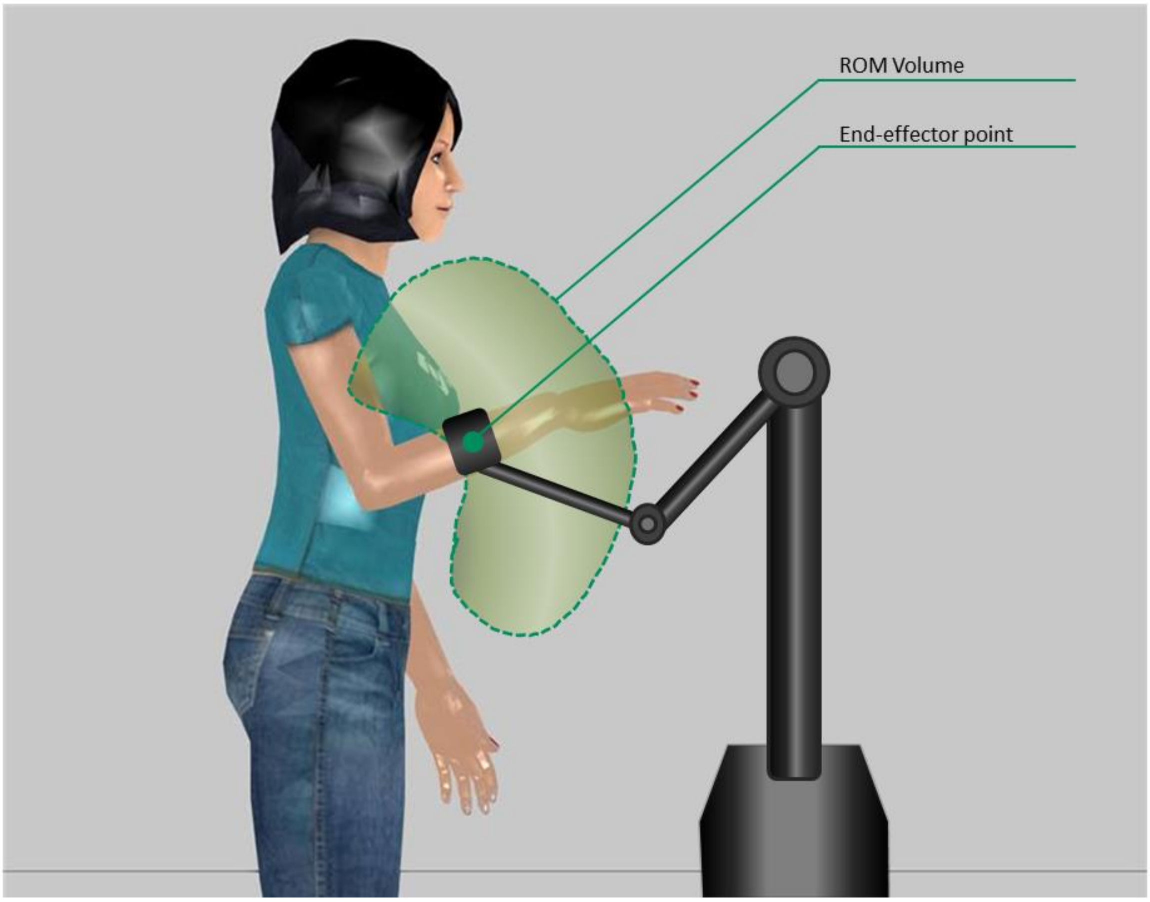

Figure 1: Exemplary application featuring situation

The hazardous situations considered in this protocol are:

- over stretching of the subject/user joints/limbs, where the distance between a proximal and a distal joint is too large.
- the robot arm moving through a space where a subject's body parts are located.

2.2 Target Behavior and Metrics of the Safety Skill

The target behavior of the skill to be validated is to validate whether the rehabilitation robot keeps the relative displacement between a reference point* and the monitored point* within the specified ROM*.

Depending on the use and implementation of the RACA* robot, the movement path that the robot will follow, while moving between these two points, can be either via a Pre-defined path* or a Direct path*.

The shape of the ROM* for which this test needs to be performed has to be based on the use specifications of the robot, so it represents a proper normal use situation. During defining a representative ROM* description for the tests it should be considered that:

- The ROM* can take any shape and does not have to be symmetrical to the reference point.
- The shape and size of the volume will have a large impact on the validation results. Therefor a matching description of the ROM volume used by the robot should be used during data analysis

The target metrics are based on physical and measurable quantities. These quantities are the output variables for the validation. The values of the target metrics indicate if the validated skill is effective enough to achieve the specified level of risk reduction. They represent a threshold that the output values of the test must not exceed for considering the test as passed. These values for the ROM* in a 3D space can be variable during intended use and may be determined by a therapist for the individual user. Therefore, the systems' ability to keep the end-point within the set safe area needs to be validated using different settings for both the endpoint setting and the area where the other parts of the body would be.

It may also be possible that other parts of the RACA* robot move through spatial areas where other body parts of the patient are. It would be good to note during this test whether parts of the RACA* robot are kept away from other body parts of the subject.

For this validation protocol, the target metrics are:

- Does the monitored point* move outside the defined ROM*? (TRUE/FALSE)
- Does any part of the robot enter an area where it may collide with any part of the body? (Yes/No)

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

3 Conditions

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

3.1 System

The term system refers to the rehabilitation robot consisting of:

- a robot arm, that is intended to move that body part within a specified workspace (ROM*)
- a base the robot is mounted on, which is also connected to the support base for the subject
- optionally a cuff or splint attached to the monitored point* of the robot arm to fixate a single body part

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

- Invalid sensor data that may influence the controller behavior or the risk reduction measure (RRM)
- Failure of an actuator that may influence the behavior of the controller or the RRM
- Etc.

This protocol can also be applied with a subsystem the robot arm is mounted on, provided that the subject is also placed on the same subsystem, where the location and the basic orientation of the robot arm system retain their mutual spatial relation (e.g. when the RACA* robot is attached to a wheelchair or a treadmill).

This protocol can also be applied when an applied part is connected to the endpoint of the robot. E.g. a splint that is, in normal use, connected to a body part of the subject with the intention to move that body part. For the validity of the protocol the movements of this applied part predictable in relation to the motions of the robot arm.

This protocol does not consider a robot arm with other kinds of sub-systems where the relation between the robot arm and the relevant proximal joint of the subject is not well defined.

3.2 Environment

Environmental conditions may influence the safety skill, depending on the implementation. When applicable the validation tests should be performed under different environmental conditions, that are considered normal use conditions and that may have an influence on the performance of the safety skill. Examples of this could be:

- Inclination angle of the total robot (e.g. when the robot arm is mounted on a mobile robot)
- Externally induced motions/accelerations of the total combination of RACA* robot and the human (e.g. when both the RACA* robot and the human both are on the same moving platform e.g. wheelchair), since these may have a significant influence on the inertia of the entire system.

4 Setup

4.1 Sensing devices

For the validation of this safety skill, a motion tracking system is used. With this system, it is possible to measure spatial coordinates of multiple markers over time.

The required accuracy of the motion tracking is determined by the required accuracy of the measurements that is derived from the risk assessment. As a guideline: An acceptable accuracy can be about 10 mm, but other values can be acceptable if based on a proper risk assessment.

The acquisition rate used by the motion tracking system should be at least a factor 10 higher than the highest expected frequency component of the movements of the robot during the test.

4.2 Test Arrangement

The robot must be positioned in such a manner that all robot movements can be properly detected with the motion tracking system.

Markers will be placed on the RACA* robot at the monitored point* and the reference point or, should this not be feasible, markers should be placed at locations on the RACA* robot from which, during any movement of this robot, the location of the monitored point* and the reference point can be reconstructed.

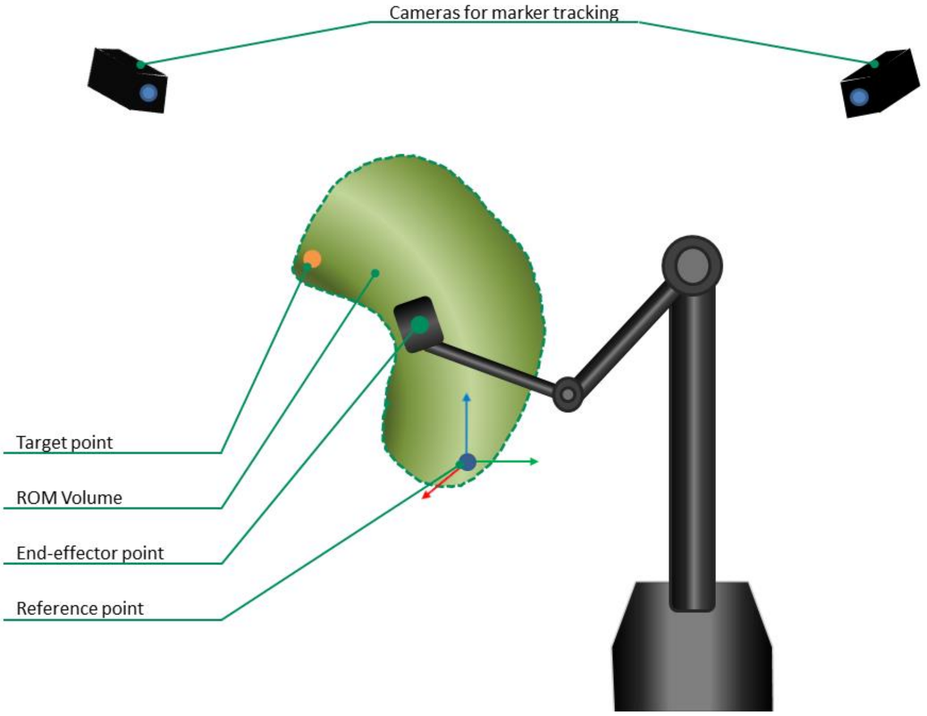

*Figure 1: General structure of the test arrangement, with defined ROM volume, cameras to register 3D coordinates, defined reference point, target point and monitored point**

The shape and size of the volume will have a large impact on the validation results. Therefor the ROM* volume used by the RACA* robot should be clearly defined. This ROM* volume definition should be used during data analysis.

A test object, representing a relevant part of the human body (e.g. torso, pelvis, other leg) that, according to the risk assessment, could be hit or crushed by the robot during normal use should also be placed in a location that is representative for a normal use situation. Markers should also be attached to that object, so a virtual representation of the human body may be recreated.

As an alternative for this marker based virtual representation of the human body also a physical object (e.g. a cardboard box - possibly equipped with sensors), that simulates the relevant part of the human body, may be used. To validate the skill for the secondary hazard, the observed physical contact with the object can be used for pass/fail detection.to refine the risk analysis / risk assessment and the severity of the impact should be validated.

5 Procedure

5.1 Test Plan

The test plan is a summary of all situations, which the risk assessment identified as hazardous due to moving the monitored point* outside a predefined ROM* volume, including all combinations of applicable conditions. Therefore, the test plan provides a detailed summary of the necessary tests to validate the skill for the considered application.

Therefor the test plan should at least cover the motion paths identified by the risk assessment as potentially hazardous. This means provoking the system to move the monitored point* into or through a spatial area that is outside of the predefined ROM* volume. The purpose of the test is to prove whether the robot exceeds this volume or not.

According to Chapter 3, the protocol must consider the following conditions:

- For defining the motion trajectories, consider that motions should at least cover
  - Trajectories of the monitored point* to locations outside the specified ROM*
  - Trajectories of the monitored point* to either locations inside or outside of the specified ROM* volume, where part of the direct path* could cross an area outside of the specified ROM* volume, should this be the shortest route
  - Trajectories where parts of the RACA* robots may collide with parts of the subject's body.
- Tests must be run at maximum speed with maximum load and under otherwise normal use conditions
- If applicable, these tests also have to be performed under system inclinations that may affect the safety skill.
- If applicable, these tests also have to be performed when the total system is subject to accelerations that may affect the safety skill.
- Repeat the tests mentioned above also under single fault conditions that may have an effect on the safety skill.

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 to prepare each part of the setup and all conditions with a significant influence on the target metrics.

- Prepare a number of test sequences and specify these in the report

5.2.1 Test Arrangement

For preparing the validation setup:

- Make sure that the environmental conditions such as lighting are appropriate for the measurement technique you are using.
- Calibrate the motion tracking system as described in its user manual or check existing calibration where applicable. Make sure the calibration accuracy meets the required accuracy.
- The robot is positioned within the capture range of the motion tracking (e.g. 3D electro-optical measurement) system.

The reference point and monitored point* as defined by target behavior (section §2.2) need to be tracked by the (3D) motion tracking system. The tracking of the reference point can be achieved:

- either by placing a marker on a stand so that it is positioned in the reference point;
- or by defining points in the environment, either on the robot or in the room, from which the location of the reference point can be accurately reconstructed;
- or by reconstructing the reference point from marker points placed on the robot (this has to be done if the reference point can move due to movements of the robot).

Optionally, for the detection of the possibility of undesired collisions with other body parts by any part of the robot:

- Position an object representing the relevant artificial body parts so potential, undesired contact between the robot and a human can be easily detected. Make sure these objects do not obstruct visibility of relevant optical markers.

The tracking of the monitored point* can be achieved in a number of ways, i.e.:

- by attaching a marker directly on the robot, if the monitored point* is defined as a point on the robot
- Or, if the endpoint is not defined as a point on the robot, either by attaching a marker on a clamp or dummy limb segment attached to the robot, or by defining points on the robot arm from which the location of the monitored point* can be accurately reconstructed.

For the definition of the target trajectories:

- Semi-randomly define an appropriate number of start and target point combinations in space outside the predefined ROM* or a movement trajectory, that could be representative for normal use situations and that would move the endpoint outside the predefined ROM for some part of that trajectory.

An appropriate number is a set of points, by which every spatial quadrant is covered at least 10 times, and from which the directions of the movements are varied.

- For non-convex ROM*: Points within the ROM* volume can be reached via a linear path through an area that is outside the ROM*, at least ten of such trajectories should be validated as well.
- For linear trajectories, document the used start and target point combinations (e.g. in Annex A). For predefined path trajectories, make sure to keep a log of the settings used for the used paths.

5.2.2 System Conditions

Please report the system composition for each single test using the form in Annex A.

- Payload during tests should be the maximum normal use load
- Velocity during tests should be the maximum velocity that the robot can achieve
- Use conditions:
    - Use as a motor driven system
    - normal use condition
    - but also consider single fault condition(s)
- In case of an emergency stop, a system may behave differently. When a robot may actively move the monitored point* back to a predefined location, and if it might be possible that the monitored

point* moves through an area that is not allowed by the ROM area setting, this situation should be validated as well

- In case during movements, if other parts of the robot may also move through an area that is potentially hazardous, these situations should be noted. The safety of these impacts should be validated via a suitable protocol.

5.2.3 Environmental Conditions

The validation tests should be performed under conditions similar to the normal use conditions.

However, if environmental conditions may have an effect on the safety skill, the test should be performed under these different environmental conditions, or simulated versions of these conditions as well.

5.3 Test Execution

Activate the measurement equipment

- Make sure the measurement equipment is calibrated (if calibration is required)
- Make sure data logging is ready for recording on all recording devices.
- Make sure all sensors are attached properly, especially when a previous execution of the protocol resulted in a collision or sudden stop of the RACA* robot

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

- Instruct the robot to move the monitored point* to a predefined starting position.
- Make sure the monitored point* of the robot is stationary for at least 1 second.
- Instruct the robot to move the monitored point* to the first target point on the list at maximum velocity.
- After a successful motion, make sure that the robot end effector* point is stationary for at least 1 second before continuing.

Repeat this with all start point and target point combinations.

5.4 Data Analysis

To determine whether the system passed this test:

- The measured location data may be filtered to remove high frequency measurement inaccuracies, but this filter may not use a cut-off frequency lower than 5 times the highest expected frequency component of the robot during the test.

- Results from the data analysis will result in a pass or no-pass. A pass will be when the results of the validation tests show that at no instant the monitored point* moved outside of the ROM* volume.
- A no-pass will occur when the monitored point* moves outside the ROM* volume, where the accuracy of the measurement system is taken into account.
- Very short “overshoots” of less than 100 ms, with a magnitude of less than 5% of the ROM distance (with a maximum of 20 mm) at that point will not count as a no-pass.

5.5 Report

The following data needs to be present in the documentation:

- Descriptions of the various test sequences executed
- Start/end point + direct path / prescribed path
- Robot speed under which the tests were performed
- Load applied to the robot
- System conditions (normal, single fault, functional stop/reset, emergency stop)
- Pass or no pass result derived from analyzed data (yes/no)
  - Within ROM*: Provide logging/tracking information.
  - No collisions of any robot with any part of “body”: Provide logging/tracking information

6 Bibliography

IEC 60601-1:

IEC 80601-2-78:2019

7 Annexes

A Report Form

Avoid single axis rotation beyond pre-set limits for individual PATIENT movement

Test Report Form for ROB-LRM-2						
Test date			**Name of tester:**			
Sequence ID (Seq#)			**Hazard ID**			
Description of RACA* robot under validation						
Measurement system used:						
Calibration date:			**Measurement accuracy:**			
Condition	Normal/S.F.C.*		**Description (S.F.C.*):**			
			Functional stop?			
			Emergency stop?			
			Max velocity (m/s)			
			Applied load (kg)			
			Inclination angle (˚)			
			Total system acc (m/s^2)			
Test ID (Seq#-id)	**Startpoint**	**Endpoint**	**Path direct* /predefined* (D/P)**	**Stayed in ROM* (Y/N)**	**Collisions (Y/N)**	**Pass? (T/F)**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**

	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
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	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	**Start**	**End**	**D/P**	**In ROM***	**collisions**	**Pass?**
	Pre defined path reference:					
	Actual path reference					

Seq#-ID	Start	End	D/P	In ROM*	collisions	Pass?
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	Start	End	D/P	In ROM*	collisions	Pass?
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	Start	End	D/P	In ROM*	collisions	Pass?
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	Start	End	D/P	In ROM*	collisions	Pass?
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	Start	End	D/P	In ROM*	collisions	Pass?
	Pre defined path reference:					
	Actual path reference					
Seq#-ID	Start	End	D/P	In ROM*	collisions	Pass?
	Pre defined path reference:					
	Actual path reference					

Final Information about test

Date of testing	
Name of tester	
Overall conclusion	
Signature	