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Award project Acronym: **DOROTHY**

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(*) Dissemination Level

PU Public

PP Restricted to other programme participants (including the Commission Services)

RE Restricted to a group specified by the consortium (including the Commission Services)

CO Confidential, only for members of the consortium (including the Commission Services)

Award Project Abstract

The DOROTHY proposers accumulated knowledge on how to tackle the issues of design for safety throughout the incremental design, development, and testing process of the REHAROB Therapeutic System in the last two decades. Just as we did with REHAROB, other developers of healthcare robots including rehabilitation robots had to adhere to a number of intertwining laws and standards: the MDD, the MDR, the ISO13485, the IEC60601, the internal rules and guidebooks of the Notified Bodies, and the same documents of the Test Organisations. Making a product out of an idea was a real nightmare.

The members of the DOROTHY consortium discontinue to revise the REHAROB Therapeutic System on industrial robot basis by changing the existing ABB IRB140 and ABB IRB 1600 force-controlled industrial robots to open control cobots of Universal Robots: UR5e and UR10e. The UR10e via a two robotic finger hand module will move the hand while the UR5e will move the elbow.

According to the IEC 80601-2-78:2019 standard for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation (RACA) the REHAROB 2.0 rehabilitation robot is classified as "arm type RACA robot for upper extremities". With the help of the COVR Award the DOROTHY project will introduce the RACA standard into the re-design of the REHAROB 2.0 rehabilitation robot. The Award project will also investigate if the use of cobots already certified according to ISO/TS 15066 in a RACA cobot system brings a technical or time advantage over a genuine design. The risk assessment document of using the RACA standard in the design for and assessment of the safety of a concrete rehabilitation robot under development was the outcome of the Award work in the period until Milestone 1.

In the second part of the DOROTHY Award project a test method to assess the safety performance of the RACA rehabilitation robot was developed in alliance with the COVR core team. The testing system is an anthropometrically adjustable and sensorized dummy limb, and the two safety skills are the limit anatomical joint range of movement and the limit anatomical joint overreaching. This outcome leads to a COVR best practice case study for risk assessment of rehabilitation robots including the recommendations on PLs and SILs.

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List of acronyms

The following abbreviations are used in this report:

ROM: Range of Motion

AAOS: American Academy of Orthopaedic Surgeons

Executive Summary

Main result of the DOROTHY Award Project is the sensorised dummy upper limb with a data processing and risk assessment software toolkit. It is a test apparatus for the automated assessment of the anatomical Joint Range of Motion Risk and the anatomical Joint Overreaching Risk of the upper limb moved by a rehabilitation robot. It also includes a structured test procedure description about the assessment of the safety skills "limit anatomical joint range of movement" and "limit anatomical joint overreaching" for the patient's upper limb actuated by a RACA rehabilitation robot.; and a software

The document describes how to process the data recorded by the sensors in the dummy upper limb. At the end of the data analysis, you get a detailed risk analysis report.

1 Introduction

This user manual contains instructions on how to process the data recorded by the sensors in the dummy upper limb (See chapter 4 in Deliverable 2.1 for more details about the sensorized dummy upper limb!). The sensorized dummy upper limb tests whether a medical rehabilitation robot avoids anatomical Joint Range of Motion Risk and Overreaching Risk during the delivered motion therapy. The Microsoft Excel spreadsheet attached (Data Analysis Sheet.xlsx) assists you in detecting the risk situations for each recorded therapeutic motion.
The spreadsheet includes two working sheets; the first sheet is where you edit the anatomical joint Range of Motion (ROM) limits and safe zones according to your organisation's standard[1] and the treated person's status! The second working sheet is where you insert the angle data measured by the sensors in the dummy upper limb (during the test) frame by frame. Here you also get the risk analysis report.
The metadata recorded for the dummy limb sensors in the Data Analysis sheet are:

- frame [number]
- time [sec]
- shoulder_extension\flexion angle [degree]
- shoulder_abduction\adduction angle [degree]
- shoulder_internal\external rotation angle [degree]
- elbow_extension\flexion angle [degree]
- wrist_supination\pronation angle [degree]
- wrist_radial\ulnar deviation angle [degree]
- wrist_ extension\flexion angle [degree]

[1] please note that, ROMs vary from organization to another.

2 Data explanation and settings

2.1 *Sheet 1 - Joint limit risk ROMs settings*

Edit here!

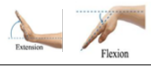
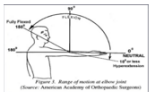
Joint	Motion type	Illustration	Range of Motion	Prohibited Zone upper limit start angle [degree]	Take Care Zone upper limit start angle [degree]	Riskless Zone [degree] from - to		Take Care Zone lower limit start angle [degree]	Prohibited Zone lower limit start angle (degree)	Percentage of take care zone
Wrist	Extension & Flexion		150	70	62,5	62,5	-72,5	-72,5	-80	5%
	Radial & Ulnar Deviation		50	20	17,5	17,5	-27,5	-27,5	-30	5%
	Pronation & Supination		160	80	72	72	-72	-72	-80	5%
Elbow	Flexion & Extension		150	150	142,5	142,5	7,5	7,5	0	5%
Shoulder	Adduction & Abduction		210	180	169,5	169,5	-19,5	-19,5	-30	5%
	Flexion & Extension		240	180	168	168	-48	-48	-60	5%
	External & Internal rotation		160	90	82	82	-62	-62	-70	5%

Figure 1: Joint limit risk ROMs settings, working sheet 1. (See chapter 2. in Deliverable 2.1 for more details about the definition of the anatomical joint angles!)

- Please note that anatomical joint angles lower than the lower prohibited zone start angles or higher than the upper prohibited zone start angles indicate forbidden postures.
- Please note that anatomical joint angles between the lower prohibited zone start angles and the take care zone lower limit start angles or between the upper prohibited zone start angles and the take care zone upper limit start angles indicate that the upper limb posture is close to a forbidden posture. The posture is considered as anatomical joint limit risk.
- Please note that anatomical joint angles between the take care zone lower limit start angles and the take care zone upper limit start angles indicate that the upper limb posture is safe.
- Please note that prohibited ROMs varies from one organisation to another and from one person to another. Please enter the upper and lower start angles of the prohibited ROMs for your organisation and the treated person in the Red cells. The ROMs already inserted into the working sheet1 are according to AAOS (American Academy of Orthopaedic Surgeons) and healthy persons[2].

[2] https://www.chegg.com/flashcards/aaos-rom-normative-values-9340014b-cb86-4a5e-a783-3c1afa86dc21/deck

- Please note that take care zones are derived from the full anatomical ranges of motion, so equal zones are considered in both upper and lower limits!

2.2 Sheet 1 - Overreaching risk ROMs setting

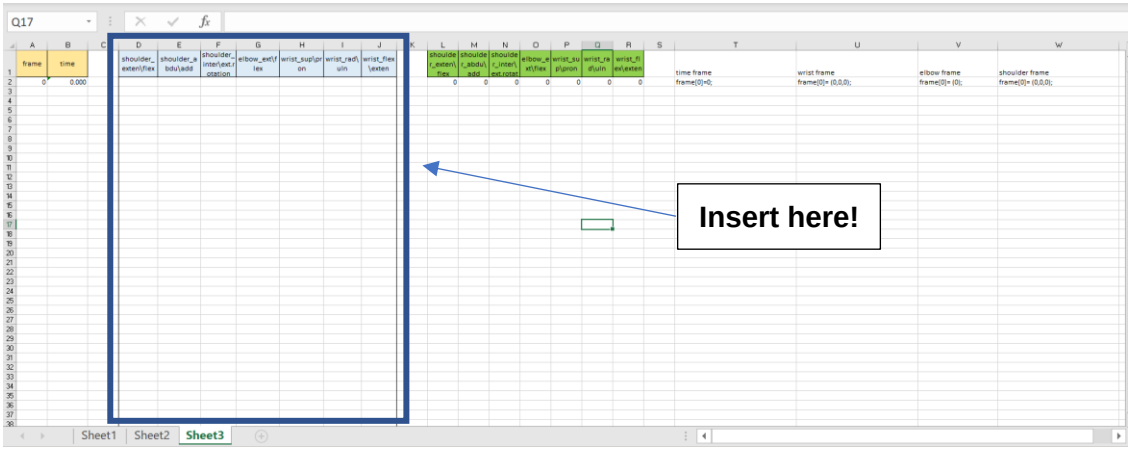
# Overreaching Risk	Only if the three anatomical joint angles are simultaneously in these ranges!	Take care zone range [degree]		Prohibited angle [degree]
wrist	Extension & Flexion	7,5	-7,5	0
	Radial & Ulnar Deviation	2,5	-2,5	0
elbow	Extension & Flexion	7,5	-7,5	0

Figure 2. Overreaching risk ROMs settings, working sheet 1

- Please note that Overreaching risk is associated with Wrist flexion & extension, Wrist Radial & Ulnar Deviation and Elbow flexion & extension simultaneously in the same posture!
- Please note that, regardless of your organisation or the treated person, the prohibited ROMs of Wrist flexion & extension and Wrist Radial & Ulnar Deviation is set to be ZERO. Manual physiotherapy exercises often extend the elbow and the wrist simultaneously while rotating only the shoulder. Such cases should be handled as exceptions.
- Please note that Overreaching risk occurs only if (within the same frame), Wrist flexion & extension is equal to ZERO, and Wrist Radial & Ulnar Deviation is equal to ZERO, and Elbow flexion & extension is equal to ZERO.
- Please note that Overreaching take care situation occurs only if (within the Same frame), Wrist flexion & extension falls into the Take care zone, and Wrist Radial & Ulnar Deviation falls into the Take care zone, and Elbow flexion & extension falls into the Take care zone!

2.3 Sheet 2 - Data Analysis

First go to sheet 3 and insert the data in the cells indicated by the blue rectangle as shown below in Figure 3.



Please, autofill the cells shown in Figure 4 as the formula already exists.

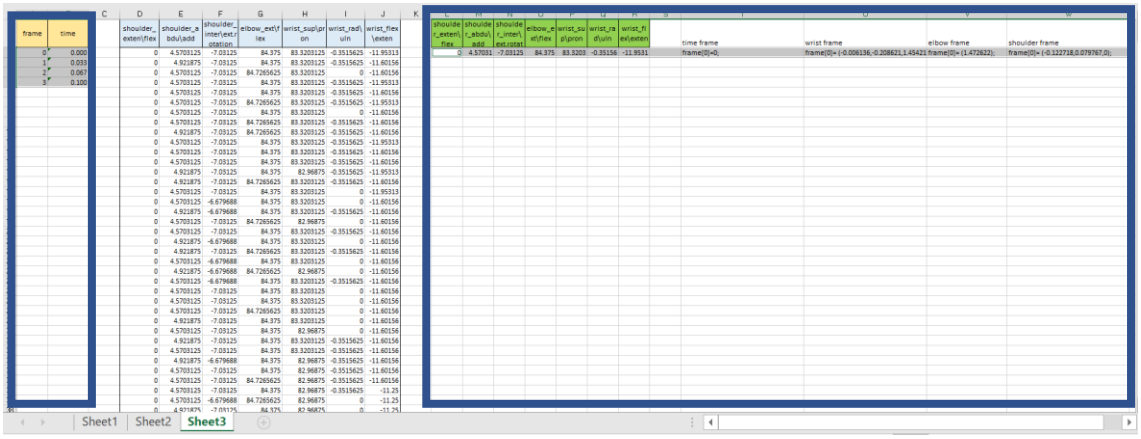


Figure 4: Autofilling of data sheet 3

After auto filling the cells, please make sure that all cells are filled in until the end of the data sheet like it is shown below in Figure 5.

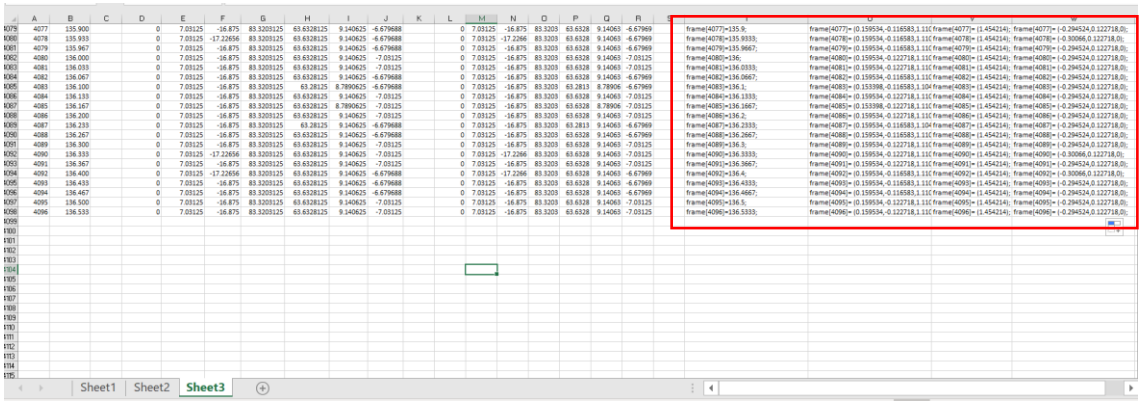
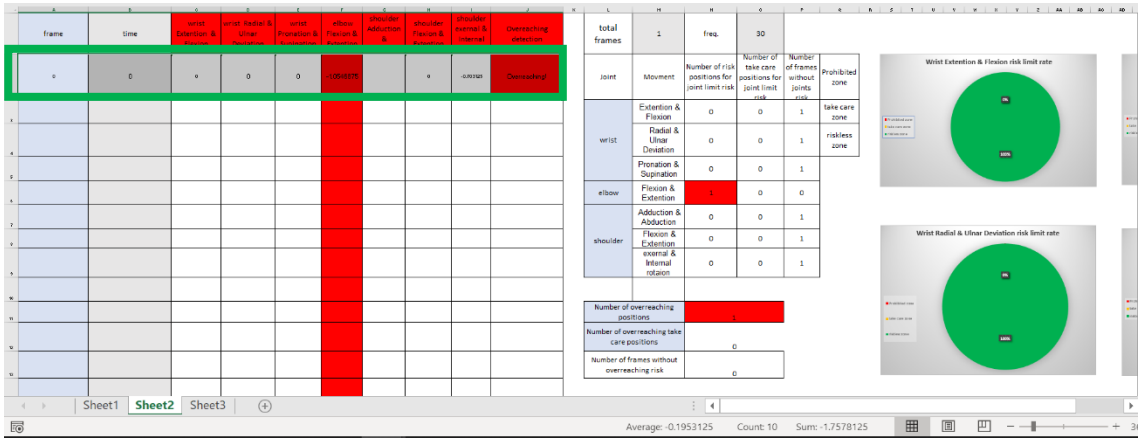


Figure 5: Checking of autofilling, sheet 3

- The cells in the red square are needed only for 3D animation, and the angles are given in radians!

Go to sheet 2 and autofill the cells in the green rectangular in the Figure 6 below as the formula already exists.

Figure 6: Autfilling of data, sheet 2



- All the data inserted in sheet 3 will be entered automatically in the correct order within sheet 2 and the result will be shown automatically!

total frames	230	freq.	30	
Joint	Movment	Number of risk positions for joint limit risk	Number of take care positions for joint limit risk	Number of frames without joints risk
wrist	Extention & Flexion	0	0	230
	Radial & Ulnar Deviation	43	2	185
	Pronation & Supination	0	0	230
elbow	Flexion & Extention	5	3	222
shoulder	Adduction & Abduction	0	0	230
	Flexion & Extention	0	0	230
	exernal & Internal rotaion	0	0	230

a)

Number of overreaching positions	1
Number of overreaching take care positions	5
Number of frames without overreaching risk	224

b)

Figure 7: a) Joint limit risk determination. b) Overreaching risk determination (sheet 2)

Figure 7(a) shows that the sum of frames having a joint limit risk for each joint is shown with the red colour and the take care zones sum of frames are shown with orange colour. Figure 7(b) shows that the sum of frames having an overreaching risk is shown with the red colour and the take care zones sum of frames are shown with orange colour.

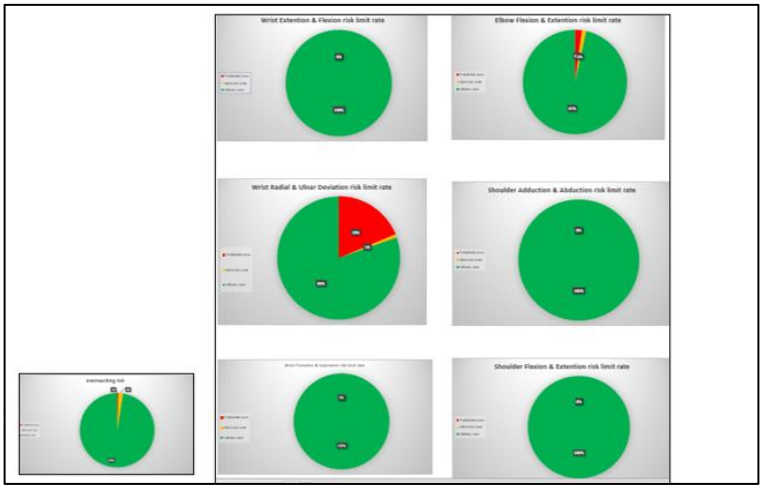


Figure 8: Seven pie charts summarize the risk situations in the report (sheet 2).

Figure 8 shows seven pie charts as the primary reporting outcomes of the risk analysis. Six of the plots are for joint limit risk rate during the test and one is representing the Overreaching risk rate during the test.

3 Example

262	8.733333333	-0.286249714	-16.20542369	-0.650650872	25.8927649	18.55323284	41.37288132	-17.2152618	Not overreaching
264	8.8	-0.286192419	-16.20536639	-0.650708168	25.89396811	18.55323284	41.37293861	-17.21514721	Not overreaching
266	8.866666667	-0.286249714	-16.20593935	-0.650708168	7.452519337	18.55351932	41.37213647	-17.21572017	Not overreaching
267	8.9	-0.000171887	-7.775724829	-0.000458366	-6.974328761	15.94472789	55.5080939	-7.084279362	Not overreaching
329	10.96666667	0	0	0	-6.530171878	16.65422153	62.39877082	-5.148484155	Overreaching!
331	11.03333333	-0.014152058	22	-0.024923664	-5.239469853	16.62809465	62.19691779	-5.135993676	Not overreaching
332	11.06666667	-0.055233131	-0.562846275	-0.097345529	-3.164961565	16.55223504	61.6103236	-5.09955356	Overreaching take care
333	11.1	-0.121237869	-0.555253399	-0.21371329	-0.369328595	16.43025232	60.66757884	-5.041054569	Overreaching take care
334	11.13333333	-0.210218215	-0.962683687	-0.370589102	3.084690177	16.26592803	59.39704493	-4.962158281	Overreaching take care
335	11.16666667	-0.320168816	-1.466141702	-0.564363428	7.134470465	16.06281449	57.82731246	-4.86469816	Overreaching take care
336	11.2	-0.44908432	-2.056402823	-0.79159849	11.71721609	15.82475053	55.98691473	-4.750450375	Not overreaching
337	11.23333333	-0.594959374	-2.72435702	-1.048741948	16.77024548	15.55534577	53.90421314	-4.621133801	Not overreaching
338	11.26666667	-0.755788628	-3.46083697	-1.332241465	22.23093434	15.25826715	-61	-4.478581901	Not overreaching
339	11.3	-0.929624023	-4.256732643	-1.638601998	28.0364292	14.93718161	49.1262035	-4.32451355	Not overreaching
340	11.33333333	-1.114402912	-5.102876715	-1.964328505	34.12410577	14.59587065	46.48779014	-4.160704917	Not overreaching
341	11.36666667	-1.308177238	-5.990159157	-2.305925942	40.43128248	14.23800121	43.72120614	-3.98893217	Not overreaching
342	11.4	-1.508941649	-6.909469939	-2.659784677	46.89522043	13.86718292	40.85487017	-3.810971479	Not overreaching
343	11.43333333	-1.714633498	-7.851584441	-3.022466961	53.45318076	13.48714002	37.91725826	-3.628599012	Not overreaching

Joint limit risk only appears within the same cell with red colour, Orange colour is an indication for take care zone

Overreaching risk only appears in this column with red colour, Orange colour is an indication for take care zone

Figure 9: Example of data analysed from previous test (sheet 2).

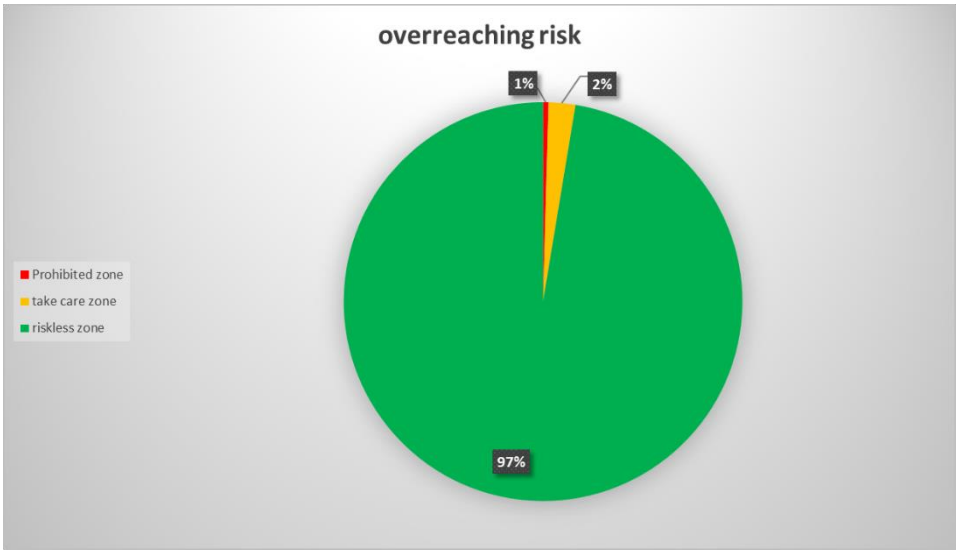


Figure 10: example for overreaching risk pie chart from previous test (sheet 2).

As it is shown in Figure 10, in 1% of the time spent during the test, the dummy upper limb was exposed to overreaching risk and only 2% of the time the dummy upper limb was approaching to overreaching risk.