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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 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 Awards 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 will be 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 will be developed in alliance with the COVR core team. Candidate functions to test are the shared control and the situation awareness subsystems (e.g. work is ongoing on full upper extremity anatomical and kinematical parameter identification purely from the data received from the two cobots, i.e. without using any external sensor system). This outcome can lead 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:

Cobot: Collaborative industrial robot

DoF: Degree of freedom

OEM: Original equipment manufacturer

Executive Summary

This document reviews 18 medical collaborative robot systems built from industrial collaborative robots.

We have found four industrial collaborative robot OEMs who deliver their products to the medical robot system integrators. These manufacturers are the KUKA AG, Germany, the Universal Robots USA-Denmark, the Stäubli, Switzerland, and the Franka Emika, Germany.

Then we analysed the standards and the regulations and how manufacturers use them.

Our ultimate reasons on why industrial cobot is so popular amongst medical application builders are threefold:

1. Industrial cobots provide the medical system builder with a low cost, very fast prototyping potential.

2. KUKA has understood the pain of the medical system builder correctly. The medically certified KUKA LBR MED reduces the need for engineering development time and testing. The other side of the coin is the net purchase costs of the LBR MED model, and the limited competitiveness as your customer pays for functions that will never be used in the commercial system.

3. There is no golden way of development. The Medical Device Regulation starts with the definition of the intended use. If the medical cobot must move an object, tool, or body part freely in the space as well as constrained under contact impedance, the industrial cobot is the cheapest product to start the development with.

1 Introduction

Two decades after 1961, when the first robot was introduced to take out parts from an injection molding machine, in New Jersey, USA, the responsible standardization committee, the ISO 184/TC 2/SC 2 defined the term “industrial robot”. While the adjective “industrial” limits the recommended use of the given type of robots to industrial automation tasks, due to their versatility, reliability, accuracy, and cost, industrial robots become popular in building non-industrial robot applications of. This trend continues to be followed even nowadays. The second chapter describes three market-leading medical robot systems illustrating the trend of building medical robot systems from industrial robots.

In the second decade of the 21st century, collaborative industrial robots appeared on the market. They pushed – among others the service robot – developers of the medical robot system to integrate industrial cobots into their applications. Our observation is the very extensive utilization of these cobot models, but the proprietary and restricted information on how much these by outlook unchanged cobot models have been changed in their mechanics, electronics, and control software remain hidden for the public. The third chapter describes all the commercially available industrial cobot based medical robot systems falling under the scope of the RACA or surgical robot standard.

Not only the professional profit-oriented but also the research-driven utilization of the industrial collaborative robots have recently been accelerated. The fourth chapter of the deliverable summarizes the most transparent non-commercial medical robot systems using one or more industrial collaborative robots. This information we find valuable for the public as field testing of the research prototypes requires research ethics approval all over the world. Thus the preparation of the technical development documentation and the safety risk assessment is a mandatory process step for the developer. We rightfully can assume that the systems shown in the chapter have passed the research ethics screening.

The fifth chapter analyses the reasons that make the industrial collaborative robots so popular among medical robot developers. The analysis uncovers technical, medical, safety, and economic arguments that can explain the development strategy.

The last chapter concludes our findings on using an industrial collaborative robot in a RACA robot system.

The source of textual and pictorial information describing the listed medical robot systems is almost exclusively the manufacturer's web page we have given the reference to.

2 Commercial medical robot systems using industrial robots

The proliferation of industrial robots triggered the utilization of modified industrial robots in medical applications such as in movement rehabilitation and assistance in orthopedic surgery required precise motion and interaction force control, accuracy, and process repeatability. By the end of the 20th century, the development of the pioneering systems was finished and forwarded to clinical testing. Two of these systems are worth mentioning. CASPAR[1], the German Computer Assisted Surgical Planning and Robotics system was used for the autonomous implantation of knee prostheses. The heart of the CASPAR system was a Stäubli RX90CR industrial robot. The upper limb rehabilitation robot MIME[2] (Mirror-Image Motion Enabler) used a PUMA 560 industrial robot. While CASPAR and MIME are discontinued; there

[1] D. Meister, P. Pokrandt and A. Both, "Milling accuracy in robot assisted orthopaedic surgery," IECON '98. Proceedings of the 24th Annual Conference of the IEEE Industrial Electronics Society (Cat. No.98CH36200), Aachen, Germany, 1998, pp. 2502-2505 vol.4, doi: 10.1109/IECON.1998.724120.

[2] P.S. Lum, C.G. Burgar, H.F. M. Van der Loos, "The use of a robotic device for post-stroke movement therapy," ICORR 1997, Proceedings of the International Conference on Rehabilitation Robotics. April 14-15, 1997. Bath, U.K., p. 79-82

are other well-accepted systems of these industrial robot based type medical systems on the market. Three of them are introduced in this chapter.

2.1 CyberKnife®

The CyberKnife® System[3], is a robot driven alternative to conventional radiotherapy. The original ideas behind the device date back to 1987 at Stanford University in the USA. There, the first commercial system was established as early as 2001, already with an integrated KUKA industrial robot. Thanks to the robotic and the image guiding technologies radiosurgery can achieve sub-millimeter accuracy. Current systems are available from Accuray. The radiation of CyberKnife® comes from a unit mounted on a tailored general-purpose industrial robot, the *KUKA* KR 240 model.

Figure 1. – CyberKnife® radiotherapy system (left), the KUKA KR IONTEC 240 industrial robot (right)

2.2 ROSA™

Figure 2. – ROSA™ surgical robot system (left), the Stäubli TX2-60 industrial robot (right)

[3] https://www.kuka.com/en-my/industries/solutions-database/2020/02/cyberknife

Zimmer Biomet's various ROSA™ systems[5] support robot assisted Total Knee Arthroplasty, cranial as well as spinal surgery. The robot assisted surgical system I includes a robot arm that is based on a general-purpose industrial robot, the Stäubli TX2-60 model.

2.3 YOMI®

The YOMI® System[6], is a dental robotic system that has revolutionized the dental implanting technology from X-Ray process via drilling to implanting. YOMI uses proprietary image guiding and haptic guiding techniques while full control of the process planning is done by an integrated software. The actuators of the YOMI® system that holds the tool and later the implant is a general-purpose light weigh industrial robot arm, the SCHUNK POWERBALL LWA 4P.

Figure 3. – YOMI® dental surgery robot system (left), the SCHUNK POWERBALL LWA 4P industrial robot (right)

3 Commercial medical robot systems using industrial collaborative robots

This chapter reviews those Medical Electrical Equipment to which – by specification or by the assumption of the authors – the IEC 60601 family of standards on Medical Electrical Equipment and the two medical robot standards: the IEC 80601-2-77 on the basic safety and essential performance of robotically assisted surgical equipment, and the IEC 80601-2-78 on medical robots for rehabilitation, assessment, compensation or alleviation apply and include an industrial collaborative robot originally intended for applications and use according to the ISO/TS 15066:2016 Robots and robotic devices — Collaborative robots.

3.1 ARTAS iX™

ARTAS iX™ is a robotic hair restoration system that reveals a very instructive development track. The first commercial and very successful version of the robot-assisted hair transplant system included a general-purpose industrial robot, the Stäubli TX-60 model.

[5] https://www.zimmerbiomet.com/medical-professionals/knee/product/rosa-knee-system.html
[6] https://www.neocis.com/

Figure 4. – First version of the Artas™ robotic hair transplant system (left), the Stäubli TX-60 industrial robot (right)

After Venus Concept Inc. acquired Restoration Robotics Inc., the 6 DOF Stäubli industrial robot has been changed to the 7 DOF KUKA LBR MED arm, the medically certified version of the industrial collaborative robot KUKA LBR iiwa.

Information sheet:

Name:	ARTAS iX
Cobot:	KUKA LBR MED
Company:	Venus Concept Inc., USA
Aim:	The system accurately visualizes and analyzes each follicular unit, while repeatedly recognizing and identifying key features at the rate of 60 times per second. Image-guided robotic alignment technology accurately and precisely harvests and implants each follicular unit at the optimal angle.
Market availability:	on market
Certification:	Medical Electrical Equipment: CE, FDA (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=5604 **:** General Surgery Devices (DHT4A))
Safety:	Restricted information.
Source:	https://www.venusconcept.com/en-gl/artas-ix.htm

Figure 5. – Current version of the Artas iX™ robotic hair transplant system (left), the KUKA LBR MED medically certified cobot (centre), the KUKA LBR iiwa industrial cobot (right)

The Artas robotic hair transplant system is the perfect justification of the applicability of a cobot with industrial roots in a medical application since a commercially successful medical robot system was transformed into a collaborative robotic system. No doubt, the two OEMs of the robotic arms, the Stäubli AG, and the KUKA AG have supported the development of the medical robotic system.

3.2 Sculptura™

Sculptura™ is a mobile platform focusing on robot-assisted intraoperative radiation therapy. The medical product utilizes state-of-the-art, patented technology with advanced features that set it apart from any other system in the oncology discipline. With the integrated KUKA LBR Med robotic arm, the mobile Directional Beam Image-Guided Radiotherapy allows for precise, fast, and localized dose delivery to the target.

Information sheet:

Name:	Sculptura
Cobot:	KUKA LBR MED
Company:	Sensus Healthcare Inc., USA
Aim:	Mobile platform focusing on robot-assisted intraoperative radiation therapy, where the robotic arm moves beam unit.
Market availability:	on market
Certification:	Medical Electrical Equipment: CE, FDA
Safety:	Restricted information.
Source:	https://www.sensushealthcare.com/sculptura/

Figure 6. – The Scuplptura™ directional beam image guided mobile robotic radiation therapy system (left), the KUKA LBR MED medically certified cobot (centre), the KUKA LBR iiwa industrial cobot (right)

3.3 CARLO®

The CARLO® system performs orthopedic surgical operations with cold ablation robot-guided laser osteotome. With the integrated KUKA LBR Med robotic, the mobile platform allows for precise and localized laser cuts on the target.

Information sheet:

Name:	CARLO
Cobot:	KUKA LBR MED
Company:	AOT AG, Switzerland
Aim:	Performs highly precise cuts with any required pattern, provide faster recovery.
Market availability:	on market
Certification:	Medical Electrical Equipment: CE, FDA
Safety:	Restricted information.
Source:	https://aot.swiss/en/carlo/

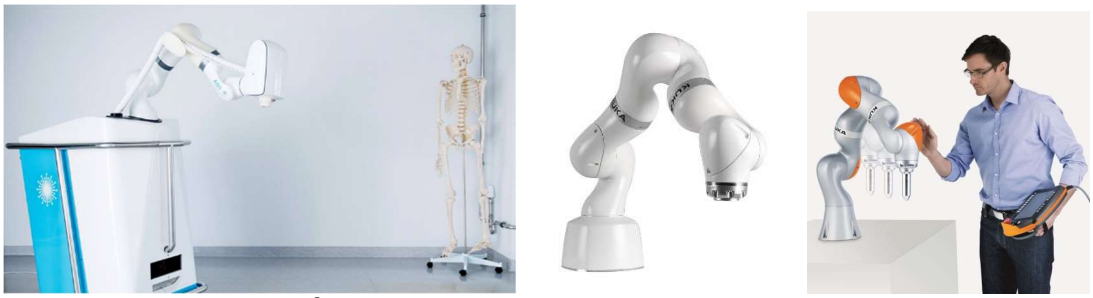


Figure 7. –The CARLO® robot-assisted cold ablation laser osteotome system (left), the KUKA LBR MED medically certified cobot (centre), the KUKA LBR iiwa industrial cobot (right)

3.4 TMS-Cobot

TMS-Cobot is a robot-assisted Transcranial Magnetic Stimulation system. TMS-Cobot integrates the industrial cobot model, the UR5 from Universal Robots Inc. for precisely moving, keeping in pose, and also in contact the Transcranial Magnetic Stimulation coil with respect to the patient's head.

Figure 8. – Specifications of the TMS-Cobot regarding cobot technology

Information sheet:

Name:	TMS-Cobot
Cobot:	Universal Robots UR5
Company:	Axilum Robotics SAS, France
Aim:	The system performs automated Transcranial Magnetic Stimulation coil placement and tracking, both in non-contact and in contact scenarios.
Market availability:	on market
Certification:	Medical Electrical Equipment: CE, FDA
Safety:	Restricted information.
Source:	https://www.axilumrobotics.com/en/tms-robot/

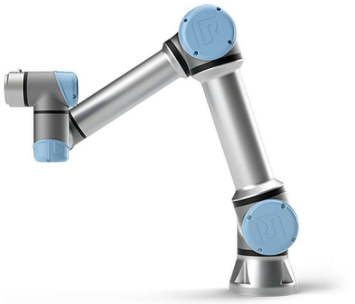


Figure 9. – The TMS-Cobot robotic Transcranial Magnetic Stimulation system (left), the Universal Robots UR5 industrial cobot (right)

3.5 ***Modus V™***

Modus V™ is a robotic digital microscope that seamlessly combines advanced engineering with the latest breakthroughs in optics, video processing, and robotic automation to deliver a new kind of operating experience. Modus V™ integrates the industrial cobot model, the UR5 from Universal Robots Inc. for precisely moving and keeping in pose the digital microscope used in neurosurgical operations.

Information sheet:

Name:	Modus V™
Cobot:	Universal Robots UR5
Company:	Synaptive Medical Inc., Canada
Aim:	The system positions a digital microscope during neurosurgical operations.
Market availability:	on market
Certification:	Medical Electrical Equipment: CE, FDA
Safety:	Restricted information.
Source:	https://www.synaptivemedical.com/products/modus-v/

Figure 10. – The Modus V™ robotic digital microscope (left), the Universal Robots UR5 industrial cobot (right)

3.6 iYU Pro

iYU Pro is a robotic system of relaxing massage for daily and business life, aiming to reduce muscle tensions. Protocols, defined by physiotherapists, are automatically adapted to the morphology of the user. iYU Pro integrates a KUKA LBR MED robotic arm for moving and pressing the massaging pad on the client's back and neck. The massaging contact force can be regulated by the user and maintained automatically by the robot.

Information sheet:

Name:	iYU Pro
Cobot:	KUKA LBR MED
Company:	Capsix Robotix, France
Aim:	The system performs an automatic and customized back and neck massage.
Market availability:	on market
Certification:	Ambiguous information: 1. The heart of the system is the KUKA LBR cobot holding the certiviate of Medical Electrical Equipment: CE, FDA 2. According to the manufacturer; https://capsix-robotics.com/iyu-pro/ : "dispositif certifié CE Machine selon la Directive machine 2006/42/CE, that means the certification under the Machinery directive
Safety:	Restricted information.
Source:	https://www.iyu.care/

Figure 11. – The iYu Pro back and neck massaging robot (left), the KUKA LBR MED medically certified cobot (centre), the KUKA LBR iiwa industrial cobot (right)

3.7 EMMA

EMMA (abbreviation for Expert Manipulative Massage Automation) is a robotic massaging system developed to provide scientific Traditional Chinese Massage assessment and professional therapeutic massage services. EMMA integrates the industrial cobot model, the UR5 from Universal Robots Inc. for precisely moving and pressing the multiple massaging rollers and pads on the client's body.

Information sheet:

Name:	EMMA
Cobot:	Universal Robots UR5
Company:	AiTreat Pte. Ltd, Singapore
Aim:	AiTreat is taking one step further to revolutionize soft tissue treatment by developing a robotic system to provide scientific Traditional Chinese Massage assessment and professional therapeutic massage services.
Market availability:	on market
Certification:	Medical Electrical Equipment: SMDR (Singaporean Medical Device regulation)
Safety:	"Your safety is of utmost importance to us. AiTreat has devoted our resources to enhance the safety of our patients. Besides having multiple layers of safety mechanisms in our hardware and software, we have developed our own proprietary technology and algorithm in addition to the existing global safety standards for collaborative robots. The force exerted by EMMA has been limited to a maximum of 100 Newtons – an impact that will feel no more painful than getting struck by a lift door (commonly 150 Newtons). Our patients can rest assure that the typical force applied during massages only ranges from between 20 Newtons to 80 Newtons, with 60 Newtons providing our users with an optimal experience. In addition, our patients have control over EMMA's features during the entire massage treatment. On top of being able to adjust the strength of the robot, our patients also have the ability to halt the procedure any time you wish, in the event of any discomfort."
Source:	https://www.aitreat.com/about-emma

Figure 12. – The EMMA Traditional Chinese Massaging robot (left and centre), the Universal Robots UR5 industrial cobot (right)

3.8 ROBERT®

ROBERT® is a movement rehabilitation robot to assist health professionals with patients who are bed-ridden. Robert can assist therapists with numerous tasks including lower limb motion therapy, which is required regularly during a patient's recovery process. ROBERT® in its early prototype used the Universal Robot UR10 industrial collaborative robot, but the current version integrates a KUKA LBR MED robotic arm for moving the orthosis mounted on the patient's shank.

Figure 13. – First version of the ROBERT® lower limb rehabilitation robot (left), the Universal Robots UR10 industrial cobot (right)

Information sheet:

Name:	ROBERT®
Cobot:	KUKA LBR MED
Company:	Life Science Robotics ApS, Denmark
Aim:	The system assists in rehabilitation of the lower limb by delivering repetitive functional lower limb movements.
Market availability:	on market
Certification:	Medical Electrical Equipment: CE (Class II a), FDA
Safety:	Restricted information.
Source:	https://www.lifescience-robotics.com/

Figure 14. – The ROBERT® lower limb rehabilitation robot (left), the KUKA LBR MED medically certified cobot (centre), the KUKA LBR iiwa industrial cobot (right)

The ROBERT® lower limb rehabilitation robot is our second perfect justification next to the ARTAS™ hair transplant robot, of the benefit a medically certified cobot can bring to the manufacturer over an industrial cobot. At first glance, both at ARTAS™ and at ROBERT® an existing and successful medical robot system was transformed into a collaborative medical robotic system without changing the function.

4 Non-commercial medical robot systems using industrial collaborative robots

This chapter reviews those medical robot prototypes that were aimed to conform to the Medical Electrical Equipment family of standards and can be classified as surgical or rehabilitation robots. The listed prototypes were developed based on cobots, but either

because of business reasons or pure research reasons, have not been developed further into commercial products.

4.1 ALEX

ALEX is a dual arm robotic massaging system to deliver safe full body massage therapy. ALEX integrates two pieces of the industrial cobot model, the UR10 from Universal Robots Inc. for precisely moving and pressing the multiple massaging rollers on the client's body. The company is raising funds required for commercial product development.

Information sheet:

Name:	ALEX
Cobot:	Universal Robots UR10 (2 pcs)
Company:	Massage Robotics, USA
Aim:	Full body massage.
Market availability:	business prototype
Certification:	-
Safety:	-
Source:	http://massagerobotics.com

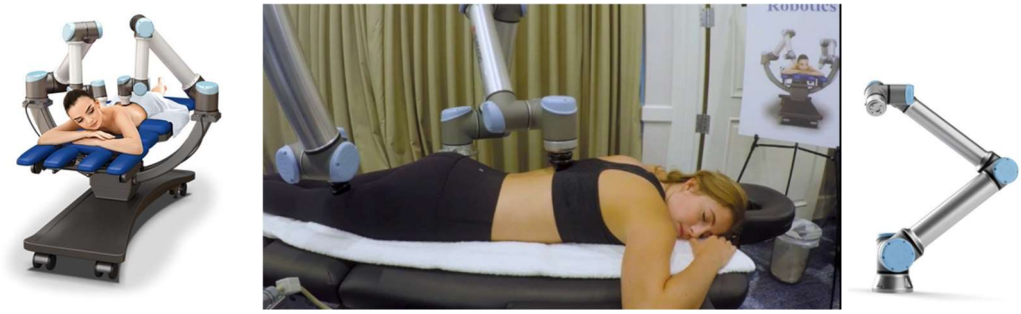


Figure 15. – The ALEX full body massaging robot (left and centre), the Universal Robots UR10 industrial cobot (right)

4.2 RAINER

The Patient@Home Project was developed by the Odense University Hospital Neurorehabilitation Centre in Ringe, and Universal Robots, to assist people rehabilitating from blood clot and stroke related injuries. The service robot is called Rainer (Universal RoboTrainer) and is designed to help patients with repetitive functional movements as part of their rehabilitation process. RAINER integrates the industrial cobot UR10 from Universal Robots Inc. for moving the patient's hand. The news we have found about RAINER is quite old, and it seems the development discontinued after making the picture shown.

Information sheet:

Name:	RAINER
Cobot:	Universal Robots UR5
Company:	Odense University Hospital Neuro-rehabilitation Centre, Denmark
Aim:	Promote rehabilitation by repetitive functional upper limb movements.
Market availability:	research prototype
Certification:	-
Safety:	-

Source:	http://www.en.patientathome.dk/projects/rehabilitation-using-industrial-robots-universal-robotrainer.aspx

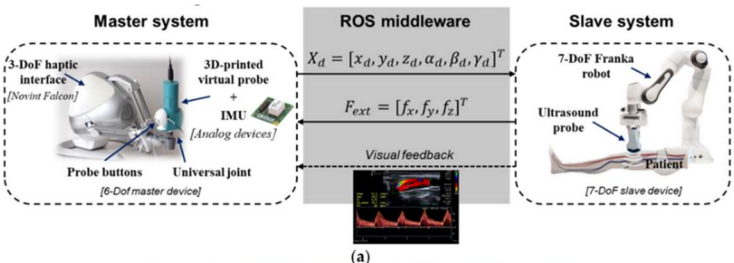
Figure 16. – The RAINER upper limb rehabilitation robot (left), the Universal Robots UR5 industrial cobot (right)

4.3 Cobot for Doppler Sonography

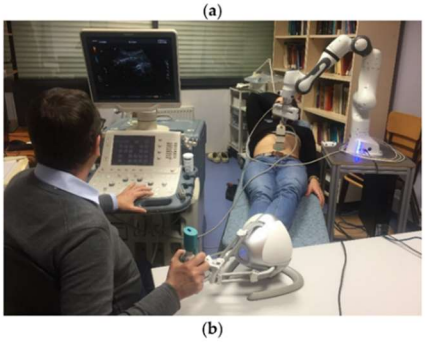
The Cobot with Prismatic Compliant Joint Intended for Doppler Sonography is a master-slave robotic diagnostic system, which integrates the 7 DoF industrial cobot model, the Panda from Frank Emika AG for moving and keeping in contact with the patient's body the doppler sonography unit.

Information sheet:

Name:	Cobot with Prismatic Compliant Joint Intended for Doppler Sonography
Cobot:	Franka Emika Panda
Company:	University of Poitiers, France
Aim:	Master-slave doppler sonography robotic diagnostic system.
Market availability:	research prototype
Certification:	-
Safety:	Safety screening by Research Ethics Committee
Source:	Cobot with Prismatic Compliant Joint Intended for Doppler Sonography by Juan Sandoval, Med Amine Laribi, Saïd Zeghloul, Marc Arsicault and Jean-Michel Guilhem, Robotics 2020, 9(1), 14; https://doi.org/10.3390/robotics9010014



(a)



(b)

Figure 17. – The Doppler Sonography Cobot (left), the Franka Emika Panda industrial cobot (right)

4.4 DynamicDentalArm

According to the source of information (See the last row in the table below.): “The dynamic dental arm, is a robotic arm that is used in dental clinics for filming dental operations, in this project I got the opportunity to develop the control software. This control software allows the dentist to control the camera attached at the end of the robot in friendly way, using wireless 3D Space-Mouse and a friendly user interface.” The DynamicDentalArm integrates the industrial cobot model, the UR10 from Universal Robots Inc. for precisely moving the camera during dental operations.

Information sheet:

Name:	DynamicDentalArm
Cobot:	Universal Robots UR10
Company:	Unknown
Aim:	Robotic system fro filming dental operations.
Market availability:	business prototype
Certification:	-
Safety:	-
Source:	https://mohammadsafeea.weebly.com/dynamicdentalarm.html


Figure 18. – The DynamicDentalArm robotic filming system (left), the Universal Robots UR10 industrial cobot (right)

4.5 BROCA

In 2015, “a groundbreaking innovation in Spain called The Broca Project, was developed by Tecnalia and The University of Malaga to assist surgeons with laparoscopy procedures. Three robotic arms from Universal Robots were incorporated into this piece of technology so engineers could easily adapt the software to the specific needs of the patient and the required tasks”.

Information sheet:

Name:	BROCA

Cobot:	Universal Robots UR5 (3 pcs)
Company:	Tecnalia and The University of Malaga, Spain
Aim:	Three-arm robotic system performing laparoscopy procedures..
Market availability:	research prototype
Certification:	-
Safety:	Safety screening by Research Ethics Committee
Source:	https://www.universal-robots.com/about-universal-robots/news-centre/universal-robots-ur5-chosen-for-the-broca-project-the-first-surgical-robot-made-in-spain/

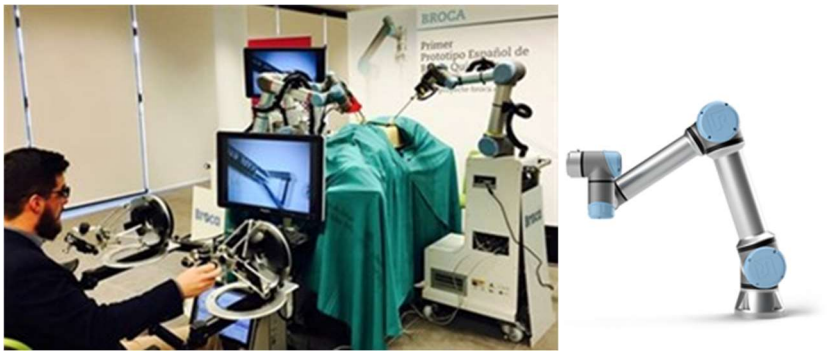


Figure 19. – The BROCA three-arm robotic laparoscopy system (left), the Universal Robots UR5 industrial cobot (right)

4.6 Chinese robot dentist

"Chinese robot dentist is first to fit implants in patient's mouth without any human involvement. Successful procedure raises hopes technology could avoid problems caused by human error and help overcome shortage of qualified dentists. A robot dentist has carried out the first successful autonomous implant surgery by fitting two new teeth into a woman's mouth, mainland media has reported. Although there were human medical staff present during the operation, they did not play an active role while it was being carried out. The one-hour procedure took place in Xian, Shaanxi, on Saturday, according to Science and Technology Daily. The implants were fitted to within a margin of error of 0.2-0.3mm, reaching the required standard for this kind of operation, experts said. The technology was designed to overcome mainland China's shortage of qualified dentists and frequent surgical errors."

Information sheet:

Name:	Chinese robot dentist
Cobot:	Universal Robots UR5
Company:	Fourth Military Medical University's affiliated Stomatological Hospital and Beihang University in Beijing, China
Aim:	Robotic system performing dental surgery procedures.
Market availability:	research prototype
Certification:	-
Safety:	Safety screening by Research Ethics Committee
Source:	https://www.scmp.com/news/china/article/2112197/chinese-robot-dentist-first-fit-implants-patients-mouth-without-any-human

Figure 20. – The Chinese robot dentist (left), the Universal Robots UR5 industrial cobot (right)

4.7 inRehaRob

"The RWTH Aachen University uses a KUKA LBR MED robot as part of its inRehaRob project. The robot guides the patient's forearm in this particular scenario. The system is designed to enable stroke patients to perform exercise repetitions independently and subsequently reinforce the efficiency of the therapy and solidify long-term recovery. DIERS International GmbH is responsible for the human-machine interface that allows intuitive interaction. Sensors made by EvoSense Development GmbH capture and analyze the movements and muscle activation levels. This technology resembles the innovative end effector-based approach, where the robot merely guides the distal end of the arm - the hand - while the patient independently performs the movements of the proximal joints - shoulder and elbow motions."

Information sheet:

Name:	inRehaRob
Cobot:	KUKA LBR MED
Company:	RWTH Aachen University, DIERS International GmbH, EvoSense Development GmbH, Germany
Aim:	The system assists in the rehabilitation of the upper limb by delivering repetitive functional lower limb movements.
Market availability:	research prototype
Certification:	Medical Electrical Equipment: CE, FDA
Safety:	Safety screening by Research Ethics Committee
Source:	https://www.medica-tradefair.com/en/Newsletter/Newsletter_2019/MEDICA-Newsletter_from_06_26_2019

Figure 21. – The inRehaRob upper limb rehabilitation robot (left), the KUKA LBR MED medically certified cobot (centre), the KUKA LBR iiwa industrial cobot (right)

5 Conformance of industrial collaborative robots to medical collaborative robots

First, in this chapter the medical collaborative robot standard is compared with the industrial robot collaborative standard.

5.1 The RACA standard

If we read through the RACA standard (IEC 80601-2-78) [1], we might feel that, on its own, it lacks ready-to-use information for robot developers. Instead, it gives reference to other standards, most frequently its 'general standard' namely IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

In fact, the RACA standard adds only modifications to the general standard in the form of replacement, addition, and amendment.

Besides the general standard, at some points, other (collateral) standards are also referenced (e.g. IEC 60601-1-2, IEC 60601-1-3).

Supposing that other standards are not different from this aspect and they also refer to other standards frequently, it can be stated this endless chain of referencing might make the end-users (developers) overwhelmed, not to speak about the cost of acquisition of each referenced standard. Below is the list of the normative references of the RACA standard:

- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-6:2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability IEC 60601-1-6:2010/AMD1:2013
- IEC 60601-1-8:2006, Medical electrical equipment – Part 1-8: General requirements for safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2006/AMD1:2012
- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- IEC 60601-1-10:2007, Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers IEC 60601-1-10:2007/AMD1:2013
- IEC 60601-1-11:2015, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 22523:2006, External limb prostheses and external orthoses – Requirements and test methods

If we consider that industrial cobot based medical robot developers are young companies, dominantly SMEs, and even startups, it is a too complex task for them to follow the dense net of Medical Electrical Equipment family of standards.

5.2 The industrial cobot standard

The ISO/DTS 15066 standard (Robots and robotic devices — Collaborative robots) [2] guides the industrial cobot manufacturer with easily digestible information. One of them is section “A.3 Biomechanical limits” that is based on a research project (No. FF-FP 0317) conducted by Johannes Gutenberg University of Mainz, Germany [3]. In this research, onset of pain thresholds of 29 body segments were evaluated for pressure and force with the participation of 100 healthy adult subjects.

5.3 Comparison and other thoughts

At some points, the industrial cobot standard is stricter than the RACA standard. Here is an example from A.3.2 Maximum pressure and force values of the industrial cobot standard:

> *Although Table A.2 provides data for contact with face, skull and forehead, contact with these areas is not allowable. [2, p. 28]*

In the industrial cobot application examples, we can see that sometimes the contact with the face, skull, and forehead is part of the normal operation.

The possible reason that we cannot find explicit force/torque values in the RACA standard is that the purposes of such devices are diverse. For example, a lower limb rehabilitation cobot must exert higher forces (e.g., 130N in case of ROBERT [4]) to move the lower limb of the patient while such high forces are far in the unallowed range in case of a hand rehabilitation cobot.

Another issue is that an industrial cobot is not expected to distinguish between intentional and unexpected forces/torques and between short term and long terms contacts. At RACA robots this is, however, a fundamental safety requirement. A RACA robot must exert a given force (e.g., on the affected upper limb of a stroke patient), that force exerted on other body segments may cause pain or even injuries. RACA robots contact the patients intentionally, the contact may be ”continuous” and the patient/robot contact may be a restrain-type contact i.e. the human is at a certain point strapped to the robot. Another aspect is the fact that those robots are operating with patients which are often far more vulnerable than individuals coming into contact with an industrial robot (i.e. factory workers). Different reactions to forces due to comorbidities can lead to unacceptable complications. That is why the RACA standard cannot provide exact values for building such systems. Instead, it recommends manufacturers to perform risk assessment (citation form 201.12.101 Movement or force/torque of RACA ROBOT):

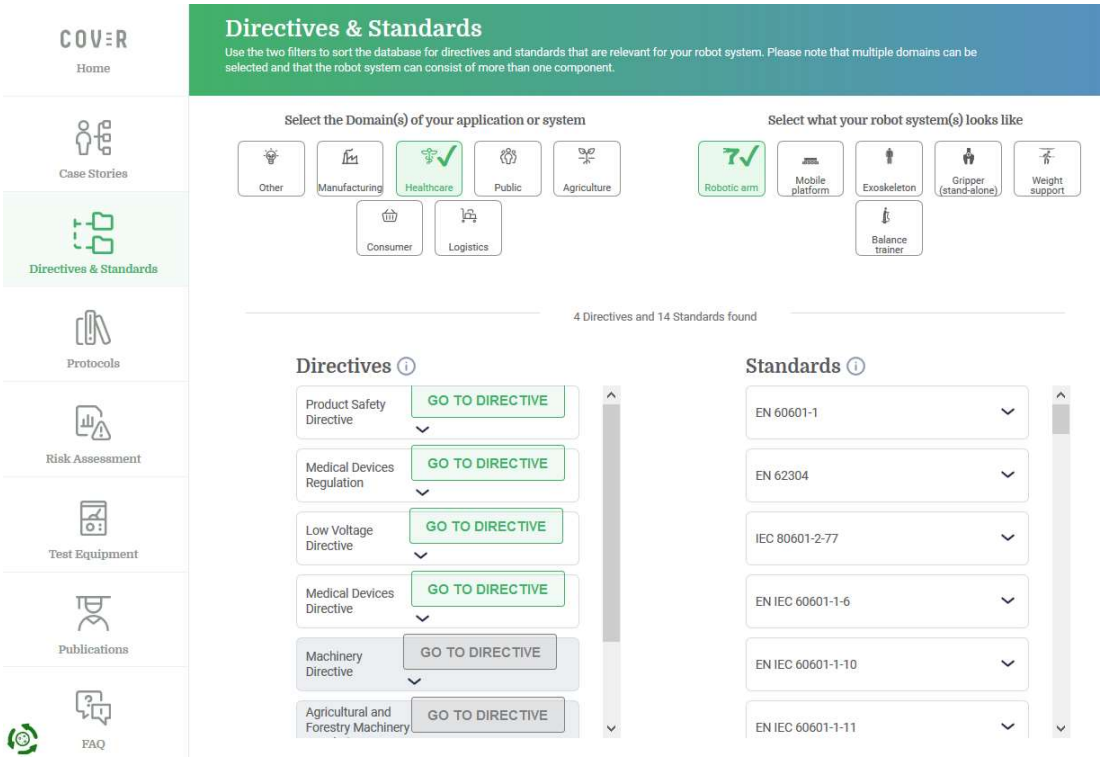
> *"The MANUFACTURER, through the RISK MANAGEMENT PROCESS, shall identify foreseeable HAZARDS related to loss or degradation of movements or force/torque of the ACTUATED APPLIED PARTS of the RACA ROBOT." [1, p. 22]*

While the aforementioned risk assessment and related testing is a compulsory part of the development of an industrial cobot based medical device, a literature research for similar projects like the above-mentioned assessment of pain thresholds or other biomechanics assessment (more specific for the aim of the investigated cobot) can save development costs and time.

5.4 Other standards and sources

5.4.1 What does the COVR Toolkit recommend?

The COVR Toolkit [5] is a good starting point for collecting the relevant standards in the field of RACA robots.



Setting the Healthcare domain and the robotic arm as our robotic system, the results of the document search will be 4 directives[7] and 14 standards[8] as following:

Directives:

- Product Safety Directive
- Medical Devices Regulation
- Low Voltage Directive
- Medical Devices Directive

Standards:

1.	EN 60601-1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	CEN
2.	EN 62304:2016	Medical device software - software life cycle processes	CEN
3.	IEC 80601-2-77	Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment	CEN

COVR Toolkit definitions:

[7] The directives are the EU legislation that your system must comply with. They are sets of legal requirements that ensures the safety of operators, maintenance personnel, equipment and the environment.

[8] Standards are the low-practical practices that should be followed to meet the requirements of the directives. Standards are not legally binding, but serves as example of good practice and should therefore always be considered when implementing a cobot system.

4.	EN IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - collateral standard: Usability	CEN
5.	EN IEC 60601-1-10:2008	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - collateral standard: Requirements for the development of physiologic closed-loop controllers	CEN
6.	EN IEC 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	CEN
7.	IEC/TR 60601-4-1:2017	Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy	IEC
8.	EN IEC 60601-2-10:2012	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	CEN
9.	EN ISO 14971:2012	Medical Devices - Application of risk management to medical devices	CEN
10.	ISO 14971:2019	Medical Devices - Application of risk management to medical devices	ISO
11.	EN ISO 22523:2006	External limb prostheses and external orthoses - Requirements and test methods	CEN
12.	EN IEC 62366-1:2015	Medical devices Part 1: Application or usability engineering to medical devices	CEN
13.	IEC/TR 62366-2:2015	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	IEC
14.	EN ISO 10933-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	CEN

Interestingly, the RACA standard (IEC 80601-2-78) is not included in the search results. For RACA to appear among the search results, another robot system (e.g. mobile platform, exoskeleton) must be selected. It might be just by mistake, but according to the COVR toolkit (on 08/09/2020) the robotic arm is the only robotic system that is not related to the RACA standard.

5.4.2 What guidelines are applied by the well-known cobot manufacturers?

5.4.2.1 Universal Robots

The ISO 10218-1:2006 (Robots for industrial environments — Safety requirements), which is no longer valid, defined a generalized maximum permissible contact force of 150 Newtons in the event of a collision between humans and robots. The current standard specifies this limit more precisely with a reference to ISO TS 15066. [6] [7]

5.4.2.2 KUKA

These are the key factors of the game changing by KUKA:
“The LBR Med bundles all robot capabilities that are particularly required in medical technology. KUKA supplies the LBR Med as a robotic component for integration into a medical product. This integration is surprisingly easy, as KUKA provides you with a CB Report in accordance with IEC 60601-1 and IEC 62304 for the LBR Med in cooperation with VDE[9].” [8, p. 3]

[9] *Verband der Elektrotechnik, Elektronik und Informationstechnik*

“Safe. The LBR Med sets standards with its safety structures. Its safety-rated hardware and software processes the relevant data. Functions covered by the equipment include encoder signals, force/torque sensors, safety circuit, single fault safety, safety-rated interfaces and configurable safety events – in short: everything that predestines it for medical technology. Sensitive. The LBR Med has redundant, integrated torque sensors. It can detect forces applied externally and react according to the freely programmable system responses you have specified. Benefit from its haptic capabilities for manual guidance, teleoperation with haptic support or gravity compensation. Use the LBR Med to apply predefined forces during a motion or as a compliant robot that responds adaptively to process forces. Furthermore, the integrated sensors are also used for safe collision detection, thereby enabling humanrobot collaboration (HRC).” [8, p. 4]
“KUKA Sunrise Cabinet Med unites safety control, robot control, logic control and process control of the entire system. Its interfaces, scalability, performance and openness mean that there are virtually limitless automation possibilities. In the future, it will also be possible to control multiple lightweight robots with a single controller.” [8, p. 5]

6 Conclusions

Chapters 1, 2, and 3 list 18 medical collaborative robot systems built from industrial collaborative robots. We have found only four industrial collaborative robot OEMs who deliver their products to the medical robot system integrators. These manufacturers are the KUKA AG, Germany, the Universal Robots USA-Denmark, the Stäubli, Switzerland, and Franka Emika, Germany.

Chapter 4 analysed the standards and the way how manufacturers use them.

Our ultimate reasons on why industrial cobot is so popular amongst medical application builders are threefold:

1. Industrial cobots provide the medical system builder with a low cost, very fast prototyping potential.
2. KUKA has understood the pain of the medical system builder correctly. The medically certified KUKA LBR MED reduces the need for engineering development time and testing. The other side of the coin is the net purchase costs of the LBR MED model, and the limited competitiveness as your customer pays for functions never be used in the commercial system.
3. There is no golden way of development. The Medical Device Regulation starts with the definition of the intended use. If the medical cobot must move an object, tool, or body part freely in the space as well as constrained under contact impedance, the industrial cobot is the cheapest product to start the development with.

7 Sources

[1] „IEC 80601-2-78:2019 Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation”.

[2] *ISO/TS 15066:2016 Robots and robotic devices — Collaborative robots.*

[3] M. Melia, M. Schmidt, B. Geissler, J. König, U. Krahn, H. J. Ottersbach, S. Letzel and A. Muttray, “Measuring mechanical pain: The refinement and standardization of pressure pain threshold measurements,” *Behav Res,* vol. 47, p. 216–227, 2015.

[4] “Lifescience Robotics - ROBERT® Specifications,” [Online]. Available: https://www.lifescience-robotics.com/specifications/.

[5] „COVR Toolkit," [Online]. Available: https://toolkit.safearoundrobots.com/toolkit/documentfinder.

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[8] "KUKA - News," KUKA, [Online]. Available: https://www.kuka.com/en-de/press/news/2017/08/kuka-lbr-med-for-integration-into-a-medical-product.