
**ISO/IEC ROBOTICS STANDARDIZATION MEETING**

## MEDICAL ROBOTICS WORKSHOP

# PROCEEDINGS

## July 28, 2017

## Óbuda University, BUDAPEST

**http://conf.uni-obuda.hu/iso-iec-2017**

*General note: the password to all presentations is "irobmedws"*

## Overview

The Antal Bejczy Center for Intelligent Robotics (IROB) at Óbuda University was hosting the ISO TC 299/WG 1, 2, 4, 6 and IEC TC 62/JWG 35 and 36 meetings in Budapest, summer 2017. These groups are accounted for the majority of international robotics standards, and devoted to promote the scientific and technological advancement of robotics, through standardization. The current primary focus of the groups are the service robot applications.

The scope of TC 299 reads: "Standardization in the field of robotics, excluding toys and military applications." The robotic standardization is divided into six working groups:

- WG 1, Vocabulary and characteristics
- WG 2, Personal care robot safety
- WG 3, Industrial safety
- WG 4, Service robots
- JWG 5, Medical robot safety (joint with IEC/SC 62A and 62D)
- WG 6, Modularity for service robots
- SG1, Study Group on gaps and structures

Robotics is a rapidly evolving and expanding area and many issues of boundary, gaps and overlaps have been identified. These are being explored both within ISO/TC 299 and with relevant stakeholders outside. A study group (SG1 Gaps and structure) was created at the first ISO/TC 299 plenary to investigate gaps, overlaps and boundary issues and recommendations are awaited to determine future strategies to adopt.

Following a great tradition, the last day of the program was a Medical Robotics Workshop, where invited experts delivered keynote talks regarding the current achievements and upcoming research and development results in the domain. The workshop was open to the public.

The working group meeting was supported by Óbuda University and the Óbuda University Students' Union (HÖK), and endorsed by the Hungarian Standards Institution (MSZT). The event benefited from the generous support of the Austrian Center for Medical Innovation and Technology (ACMIT, www.acmit.at).

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# An Overview of the IEC/ISO 60601/80601 series of Medical Electrical Safety Standards

Michel BROSSOIT

Biomedical Senior Engineer,
Medical Technical Advisor at CSA Group

**Abstract** : All medical electrical/electronic devices used around the world need to demonstrate that they are safe and effective before they can be sold and used. The IEC/ISO safety standards used for Medical Electrical Equipment or Medical Electrical System are covered under the IEC/ISO 60601/80601 series of medical standards. These safety standards can be used for many different types of Medical Electrical Equipment or Systems. The IEC/ISO 60601/80601 series of medical standards will be used for "medical robot". These new upcoming IEC 80601-2-77 (RASE) and IEC 80601-2-78 (RACA) medical standards will play a key role for decision-makers of tomorrow. This presentation will provide the attendees a basic introduction of the IEC/ISO 60601/80601 series standards and also demonstrate the benefits of standardization concerning medical robots

**Short biography:** Michel worked actively in Health Care Facilities completing a multitude of biomedical and electro-medical trainings/courses from different renowned medical companies. He has accumulated more than 30 years of experience in the electrical/biomedical engineering field.

Michel joined CSA International (today called CSA Group) in 1998 as a Certification Engineer for Electro-medical and Laboratory Equipment. Since 2004, Michel was appointed as the Medical Technical Advisor (TA); he is responsible for the global technical decisions relating to the IEC/ISO 60601/80601 Medical Standards and other medical standards for CSA Group.

Michel is the Head of Delegation (HOD) of the TC62 Medical Canadian National Mirror Committee (CAN/CSA Standards, Canadian chairman of TC 62/SC62A and TC 62/SC62D and expert member of TC 62/SC62B and TC 62/SC62C). Member, Secretary and Chairman of International committees (IEC and IECEE) such as IEC TC62 SC62A WG14, IECEE MEE Risk Management Task Force, IECEE ETF3 (MED), IEC TC62 SC62A JW9 and IEC/ISO TC62 SC62D WG35 and WG36 - Medical Electrical Robots. He actively promotes Safety in different Medical Fields by teaching Medical Standards to different parties and R&D groups around the world.

*You can find the presentation here:*
*https://drive.google.com/file/d/0B1CLLGNiHAIpdkxoUEo4anh5Wm8/view?usp=sharing*

## On IEC 80601-2-77, the first safety standard for surgical robots

Kiyoyuki CHINZEI, Ph.D.

Project leader of IEC/SC 62D/JWG 35

National Inst. Advanced Industrial Science & Technology (AIST), Japan

**Abstract**: The latest status of IEC 80601-2-77 – the safety standard for surgical robots, or robotically assisted surgical equipment – will be presented. To date, there is no standard particularly written for surgical robots. This means that the developers must determine how to demonstrate the product safety by applying and extrapolating the ideas of other existing standards.

The new standard IEC 80601-2-77 will cover several types of surgical robots with combination of types of surgical instruments including other ME equipment such as HF surgical equipment, ultrasound probe, etc. This standard draws the 'border' between the robot and other ME equipment so that the developer can determine which standards apply to which part of the robot system.

**Short biography:** Deputy director, Health Research Institute of AIST since 2015. Adjoint Professor of Tokyo Denki University since 2005. Project leader of IEC/SC 62D/JWG 35 (Safety of surgical robot). Research works in the fields of biomedical engineering including surgical robotics, MR compatible robotics, biomechanics for surgery, and regulatory science for medical devices.

*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpbUxPWFlRN00wNkU/view?usp=sharing*

# The new upcoming IEC 80601-2-78 standard

Jan Veneman, Ph.D.

Tecnalia Research and Innovation, San Sebastian, Spain

**Abstract:** This presentation will introduce the new standard on particular requirements for basic safety and essential performance of MEDICAL ROBOTS for REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION. It will explain what types of robots are targeted by this standard and highlight the main concepts that are deviating from the general IEC 60601-1-1 standard.

**Short biography:** Dr. Jan Veneman received a M.Sc. degree in Mechanical Engineering (1998), another M.Sc. in Philosophy of Science, Technology and Society (2000), and his Doctorate (Dr.) in Biomechatronics (2007), all from the University of Twente, The Netherlands.

Currently Dr. Veneman is project manager and senior researcher in the Medical Robotics Department in the Health Division of TECNALIA. He is active in the fields of exoskeleton robotics, gait rehabilitation, gait assessment, haptic devices, exoskeletons and smart orthotic materials, and especially active in the topics benchmarking and standardization for wearable exoskeletons related to assistance and training of walking.

Since 2002 he has been active in R&D related to Wearable Robots, when he started the development and evaluation of a robotic exoskeleton for interactive gait rehabilitation (LOPES) in the University of Twente. In this research and at the Roessingh' Research and Development (NLD) centre he worked on using gait assessment techniques to evaluate exoskeletons and rehabilitation tools.

He is the project coordinator of BALANCE (http://www.balance-fp7.eu/) - and participated in HYPER - http://www.car.upm-csic.es/bioingenieria/hyper/). He is currently Spanish expert in the ISO/IEC TC299/SC JWG9 committee "Medical electrical equipment and systems using robotic technology", related to medical robotics (medical applications of exoskeletons). He also coordinates the FP7 ICT project BALANCE, focused on introducing postural and balance control into exoskeleton assistive robotics.

*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpTDhYZlM0dnI4QTQ/view?usp=sharing*

# China Medical robot standards update and CFDA regulations updates

Alvin Kuang

(CCIC-CSA International Certification CO., LTD, China)

**Abstract:**

1. China technical committee and standards update;
2. CFDA regulations regarding medical robots.

**Short biography:** Mr. Alvin Kuang holds a Master of Science degree in Engineering from Shanghai Jiao Tong University. Since 2005, he has been working for CCIC-CSA certification company, supporting medical device manufacturers with in-depth knowledge about applicable standards for medical device testing and certification especially for international market access. Mr. Alvin Kuang is in charge of CSA group Shanghai CB Laboratory. He is also registered senior inspector of CCAA (China Certification and Accreditation Association) and registered member of the National Import and Export Inspection and Quarantine personnel. In addition, Mr. Alvin Kuang is member of the International Electrotechnical Commission IEC/ISO TC 62/SC 62D, JWG 35 and 36 working group, to participate in compiling the medical robot standards, the member of China Medical Robot Standard technical committee, he is also the member of SAC TC 159 national industrial automation systems and integration standard working group.

*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpUlZBYVJHUGFkVUU/view?usp=sharing*

# Testing Standards for the Medical Rehabilitation Robot

Canjun Yang, Ph.D.

Professor of Mechanical Engineering, Zhejiang University

**Abstract :** Rehabilitation Medical Robots have been developed for a long time, Design the testing standards for the rehabilitation medical robot is very important for the word. We will collaborate with the Zhejiang medical equipment testing institute to setup this standards for Zhejiang Province in China, This presentation will show why and how to do for it.

**Short biography:** Dr. Canjun Yang received his B. S. and M. S. degrees in mechanical engineering from the Nanjing University of Aeronautics and Astronauticso in 1991 and 1994, respectively, and his Ph. D. degree in mechanical engineering from the Zhejiang University in 1997. Since 1997, Dr. Yang has been a faculty and Professor (from 2004) in the state key lab of fluid power transmission and control at Zhejiang University from 1998. In 2004, he visited at Minnesota University as an academic visitor. . From 2013 to 2014 , he visited at Washington University(Sealttle) as an academic visitor.

Dr. Yang was awarded the National Technology Invention Award (Second Prize) from the State Council in 2009, the University Technology Invention Award (First Prize) of Ministry of Education of P. R. China in 2006, Science and Technology Award of Zhejaing Province (First Prize) in 2006, Zhejiang Youth Science and Technology Award in 2009. He was selected to the Program for New Century Excellent Talents in University (NCET) and New Century 151 Talent Project of Zhejiang Province (First Class), and received the State Council Special Allowance. Dr. Yang's research interests include man-machine intelligent mechatronic system and mechatronic devices and technology for deep-sea exploitation. He took the responsibility for two projects of National Science Foundation of China and four projects of The National High Technology Research and Development Program of China (863 Program) as project leader, and has published over 100 technical papers including over50 papers are indexed in SCI/EI.

Dr. Yang is currently the deputy director of the school of Mechanical Engineering in Zhejiang University China, the member of National Technical Committee Submersible of Standardization of China, the trustee of China Innovation Strategic Alliance of Rehabilitation Technical Aids.

*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpRi0wZ0xNTkZqUEE/view?usp=sharing*

## Bringing surgical robot standards to application

Gernof Kronreif, Ph.D.
Austrian Center for Medical Innovation and Technology, Austria

**Abstract**: The presentation is about a medical robotic system developed by ACMIT, where activities have ranged from a first concept toward product transfer, certification, and finally small lot-size OEM production. Topics include a short overview of standards/regulations applied during the development phase, lessons learned, and wishes with regard to upcoming new standards.

**Short biography:** Cum-laude doctors degree in Technical Sciences from the Vienna University of Technology in 1995 - Special subject: Robotics; 1991 – 1999: Scientific/Teaching Assistant at Vienna University of Technology; 2000 - 2010: Employment at non-academic research institutions with special focus to Robotics for Service Applications; Since 2010: Scientific Director of the “Austrian Center for Medical Innovation and Technology” and head of the research area “Instruments and Robotics”. Lecturer at several “Universities of Applied Sciences” (“Fachhochschulen”). More than 140 papers and presentations at scientific conferences.

*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpU2RlLW00NDlldW8/view?usp=sharing*

# General Approval Process for MD & Progress of Medical Robot for Rehabilitation Guidance in Korea

Youngwoo BAE, Ph.D.

MFDS, Korea

**Abstract** : MFDS has an affiliated agency named NIFDS(National Institute of Food and Drug Safety Evaluation). The Medical Device Evaluation department takes charge of a Medical device approval and review.

In case of class 1 product, as class 1 has low hazard, manufacturer can register its product directly to online medical device system called 'KiFDA'. And in case of class 2,3,4 product, it should be reviewed with technical documents.

First of all, it has been that clear to make the difference between medical robots and existing MEE and MES. Secondly, we have realized that it is necessary to classify the medical robots for rehabilitation as much as possible in detail. The proposal for the definition of product code in the regulation and the classification of medical robots for rehabilitation will be briefly presented.

**Short biography:** Assistant Director, Orthopedic & Restorative Devices Division, Department of Medical Device Evaluation. Academic background: Ph.D. in Biomedical Engineering at Yonsei University, Korea (a combined master's and doctorate program) ; B.S. in Medical Electronics at Yonsei University, Korea

*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpTlpaa1dCMW14eXM/view?usp=sharing*

# Together transforming orthopedics

Stephen Still
Stryker Inc./MAKO, USA

**Abstract:** As with most areas of science and engineering there have been great advancements in the tools used. Where once men built buildings by using hammers and chisels, today there are power tools, cranes, and laser measurement tools.

The application of robotics to medicine is similarly transforming orthopedics. Surgeons can implant replacement knees and hips with a repeatable accuracy that was previously unattainable. The benefit to patients is quicker recovery, and better long term outcomes.

**Short biography:** Stephen is a Senior Staff Electrical Engineer in the Stryker Robotics group. Stephen has had responsibility for designing the Mako Integrated Cutting System electronics, architecting the power delivery system, and obtaining the 60601-1 2nd and 3rd edition approvals for the Mako robot. Stephen is currently serving as a US Expert to the IEC/ISO Joint Working Group 35 for 80601-2-77. Prior to joining Stryker/Mako Surgical, Stephen worked for IBM and RadiSys, designing analog and digital equipment, and has had extensive involvement with EMC compliance, and safety agency approvals for computer, telecom, and medical products. Stephen has European, and multiple US patents for inventions at Stryker and IBM, as well as multiple articles for inventions published in the IBM Technical Disclosure Bulletin

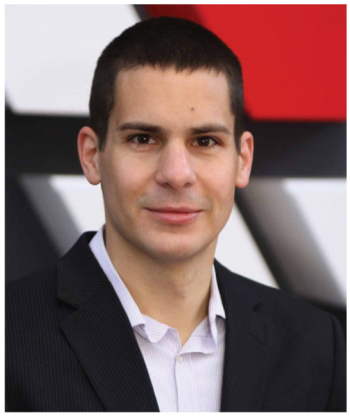
*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpTW41OUlXRjBOaG8/view?usp=sharing*

## Assessing the autonomy of surgical robots

Tamas Haidegger, Ph.D.

(Óbuda University, Hungary / ACMIT, Austria)



**Abstract**: Autonomous functions and capabilities are being developed for even commercially available surgical robotic systems, yet the regulating standards and international norms are still heavily under development. It is now time to look into the practice and applicability of the upcoming ISO/IEC standards in connection with the autonomy of surgical robots.

**Short biography:** Tamás Haidegger is an associate professor at the Óbuda University, serving as the deputy director of the Antal Bejczy Center for Intelligent Robotics. Besides, he is a research area manager at the Austrian Center of Medical Innovation and Technology (ACMIT), working on minimally invasive surgical simulation and training, medical robotics and usability/workflow assessment through ontologies.

*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpOXNNV0xZcXpaekk/view?usp=sharing*

## Collaborative robots in medical applications

Matyas Takacs

(Obuda University, Hungary)

**Abstract**: With the new approach of the collaborative robots it is possible to use them for Human-Robot Interaction. These collaborative robots can be used not just in the industry but in the clinic as well. The KUKA iiwa robot can work in medical applications (thanks to the collaborative properties, such as built in joint-level torque sensors and impedance control mode) e.g. for telemanipulation with the dVRK or for ultrasound scanning. The rosjava library and the FRI interface let us to communicate with the robot and control it through ROS. With these functionalities, the KUKA iiwa can be easily integrated with other systems through ROS.

**Short biography:** Mátyás Takács is an MSc student at the Óbuda University, and research assistant at the Antal Bejczy Center for Intelligent Robotics. He received his BSc degree in mechatronical engineer from Óbuda University. His research fields are robotics and automation.

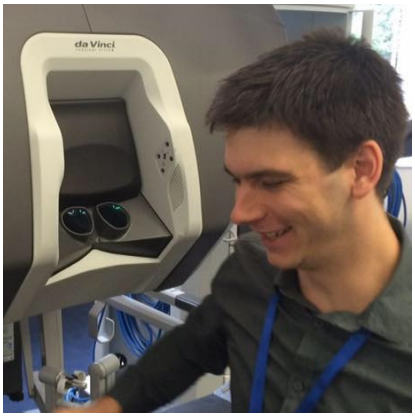
*You can find the presentation here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpMGxGUE5TXzNuaUk/view?usp=sharing*

## Understanding Surgeries Trough Modelling and Automation

Dénes Ákos Nagy, M.D.

Óbuda University, Hungary / ACMIT, Austria




**Abstract:** An important question in surgical robotics is finding the target applications for surgical automation. For these automated procedures it is essential to have a good understanding of the surgical process which, as of today, is mostly described using vague natural language. An effort towards creating a better, less ambiguous description of surgical procedures is prepared by the international OntoSPM group who's intention is to create a universal surgical ontology. Surgical Process Models (SPM) built on ontologies can provide detailed information, on several granularity levels, on how surgery is built up. We evaluated the feasibility of automation on the subtask granularity level using blunt dissection, and showed that automation is possible based on readily available sensory inputs.

**Short biography:** First received his computer engineering degree (BSc) from Pázmány Péter Catholic University in 2012. Parallel to his computer engineering studies, he also started his medical degree, and graduated as a medical doctor in 2015. He had won the HAESF internship, and spent a year at the Sheikh Zayed Institute for Pediatric Surgical Innovation (Children's natioanl Hospital, Washington DC) as a visiting researcher. He started his Ph.D. at the Antal Bejczy Center for Intelligent Robotics (IRob), and his work now focuses is on surgical process modeling.

*You can find the presentations here:*

*https://drive.google.com/file/d/0B1CLLGNiHAlpOUI3eDJ1eGw3TGc/view?usp=sharing*

*https://drive.google.com/file/d/0B1CLLGNiHAlpZFcxeGh6RktGR2M/view?usp=sharing*

*For more information, contact us at **iso-iec@irob.uni-obuda.hu***

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