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european Robotics Forum 2016

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Ongoing work on safety standardization of rehabilitation robots

ISO TC299 – IEC TC62D

Joint Working Group 36 under JWG 5

Medical Robots for Rehabilitation

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IISART is dedicated to advance and promote modern healthcare technology in rehabilitation for the benefit of the patient and society at large. The main focus is on Robotics, Virtual Rehabilitation and Therapeutic Electrical Stimulation.

IISART exists to represent the interests of companies developing, manufacturing, and marketing medical devices and their accessories and active capital medical equipment in the field of robotics and advanced healthcare technology in rehabilitation.

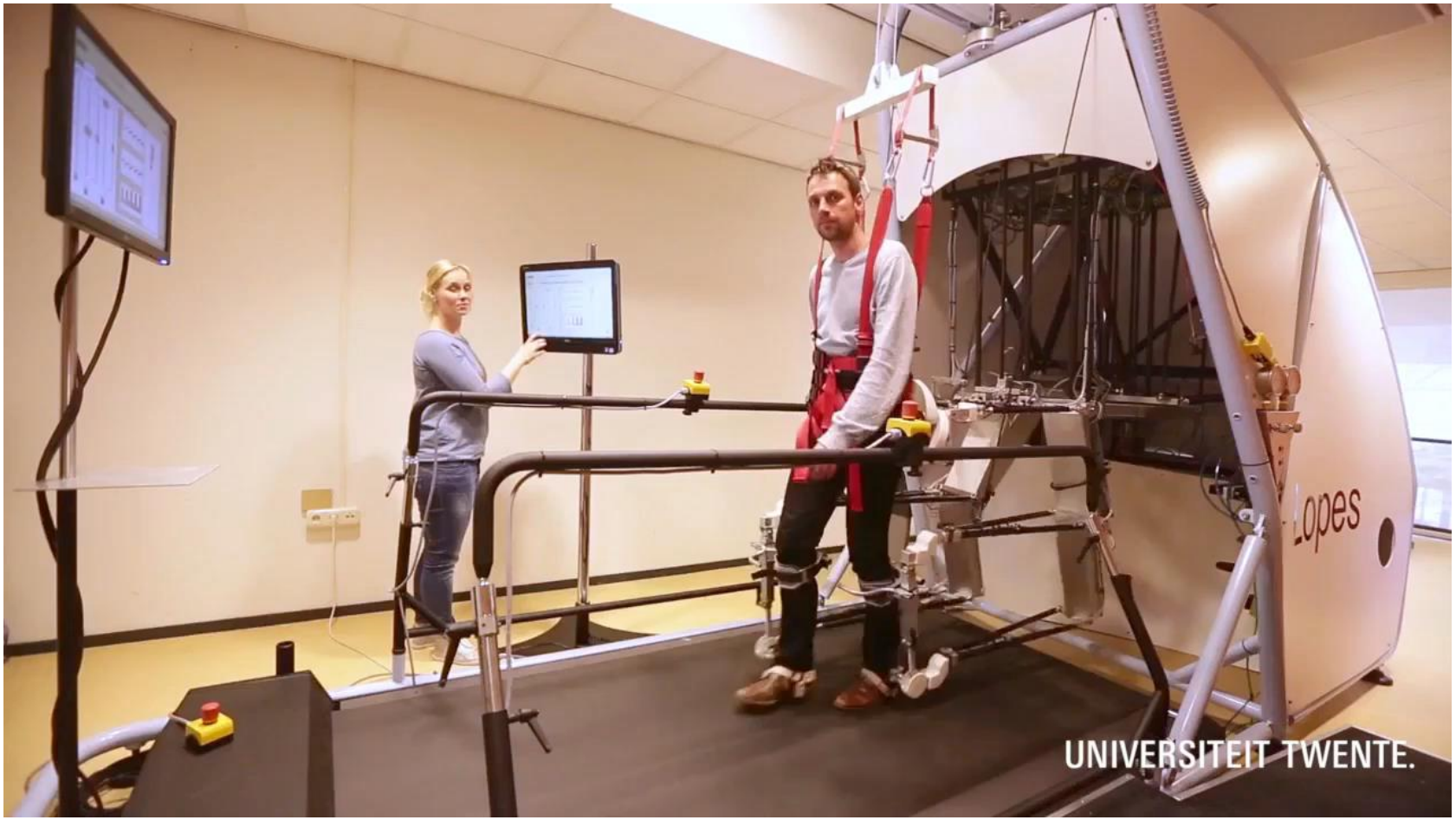
President

Dr. Gery Colombo; CEO, Hocoma AG, Switzerland

http://www.iisartonline.org/

ASSOCIATE MEMBERS


Armeo®Power
Robotic arm exoskeleton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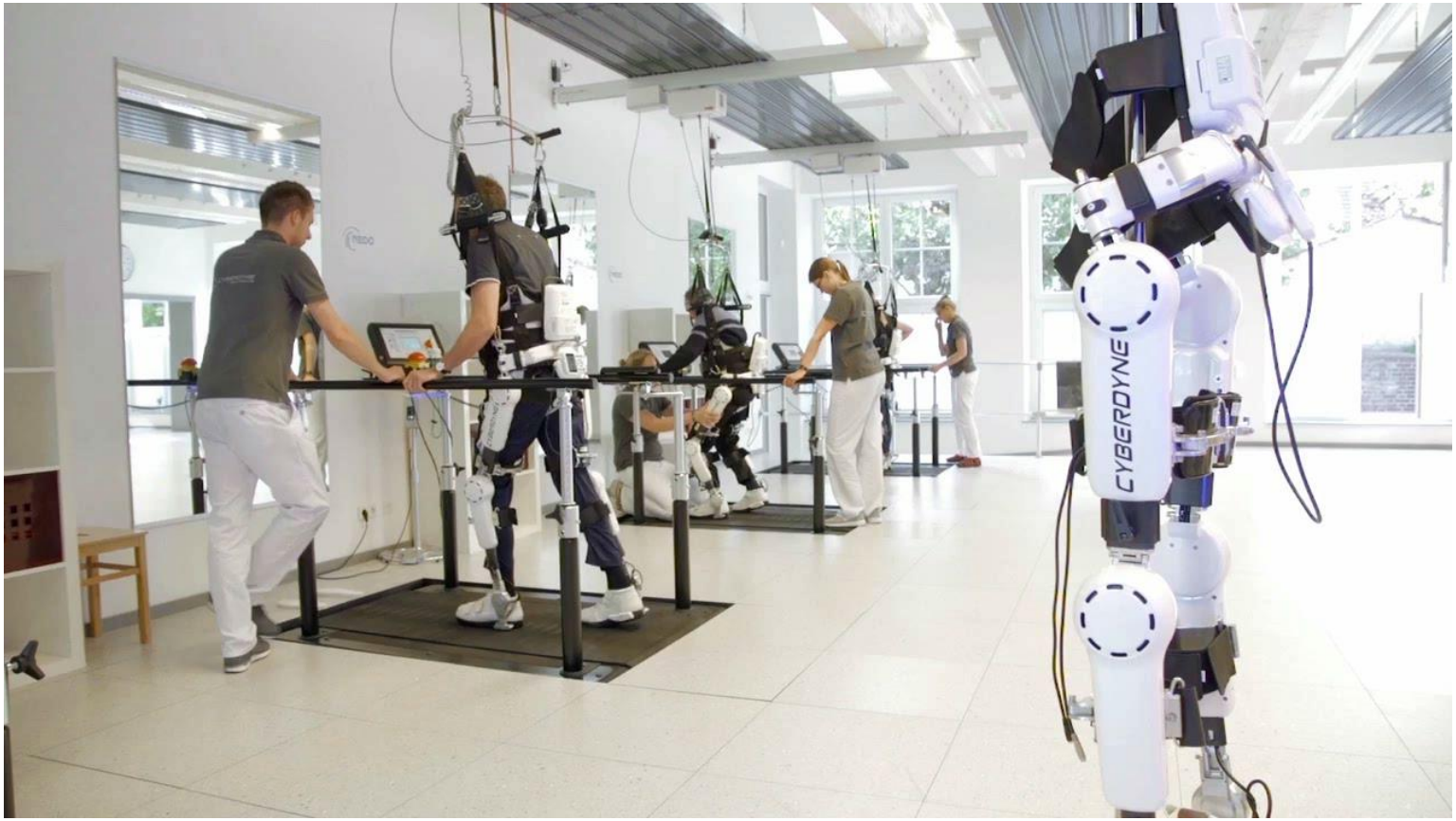
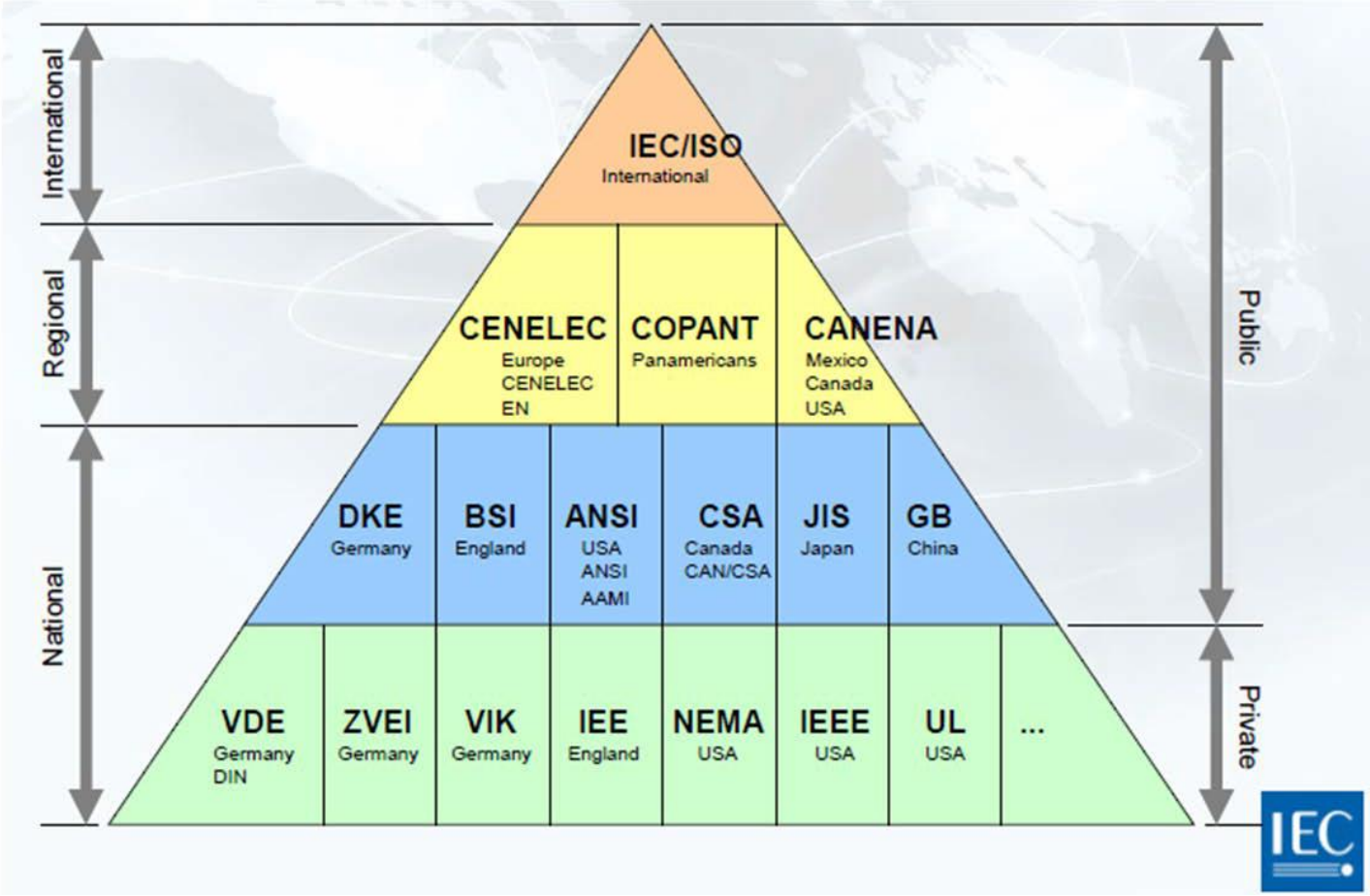


FDA is giving clearance to these devices for home use at this point (ReWalk, Parker Indego)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BSI
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ANSI
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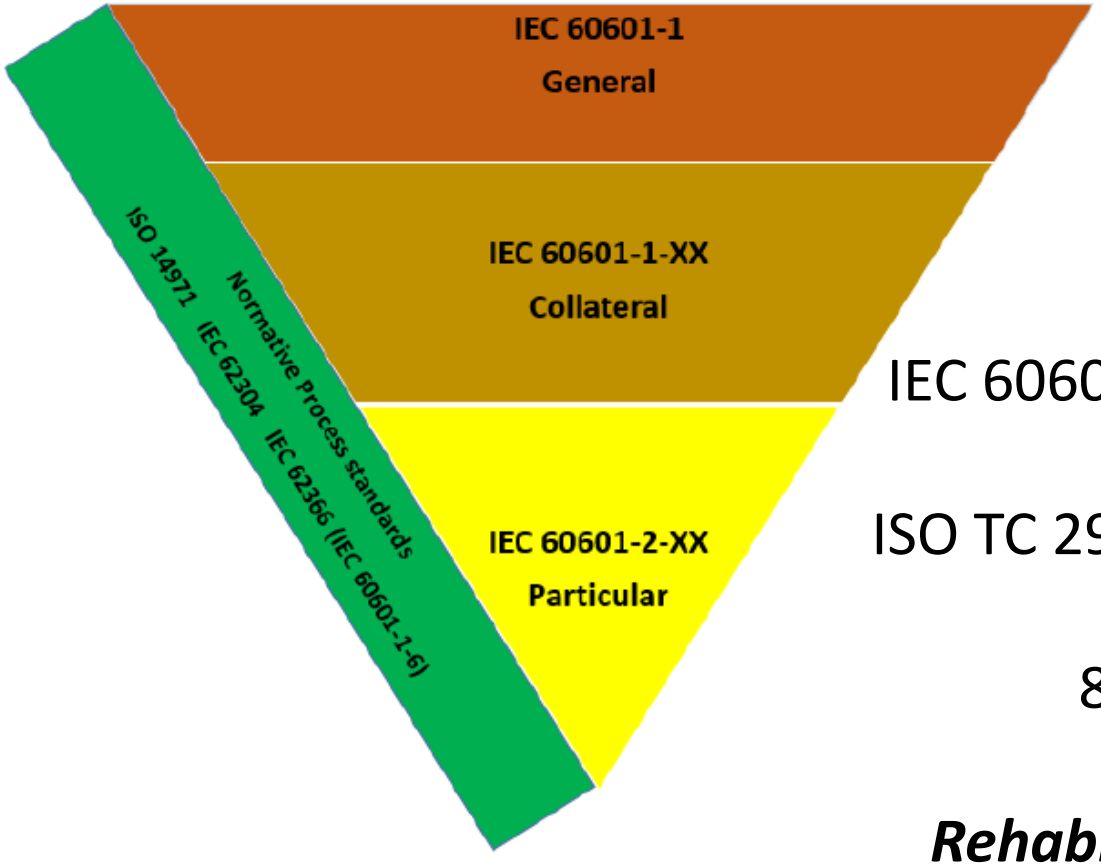

IEC 60601 – Safety of Medical Devices

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ISO TC 299 Robots and Robotic Devices

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80601 series standards

Rehabilitation Robots = Particular

New work item initiated July 2015

IEC 80601-2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, compensation or alleviation
IEC TC 62 Electrical equipment in medical practice SC62 D; Specific electromedical Equipment - includes: All activities regarding Specific Robotic Technology
JWG 35 & JWG 36 together with ISO TC 299 JWG 5 – Medical robot safety

Status
29 International Members
CDM Committee Draft;
24 Month Schedule

Last Meeting: January 2016
Arlington; DC; USA (AAMI)

Table 1 – Project stages and associated documents

Project stage	Associated document	
	Name	Abbreviation
Preliminary stage	Preliminary work item	PWI
Proposal stage	New work item proposal [a]	NP
Preparatory stage	Working draft(s) [a]	WD
Committee stage	Committee draft(s) [a]	CD
Enquiry stage	Enquiry draft [b]	ISO/DIS IEC/CDV
Approval stage	final draft International Standard [c]	FDIS
Publication stage	International Standard	ISO, IEC or ISO/IEC

[a] These stages may be omitted, as described in Annex F.
[b] Draft International Standard in ISO, committee draft for vote in IEC.
[c] May be omitted (see 2.6.4).

SCOPE:

This International Standard applies to the general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ROBOTS that physically interact with a PATIENT to support or perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION related to the patient's movement functions, following an IMPAIRMENT.

New aspects

Clarification and extension of terms and safety issues in the 60601-1 related to Rehabilitations Robots

- Specific hazards, related to the direct power exchange between robot and patient
- Specific testing methods to demonstrate safety
- Specific definitions, to define a terminology

IEC TC 62 SC62 D; IEC 80601-2-78 (draft)

Defined terms	Text
201.3.204 DEGREE OF AUTONOMY	Taxonomy based on the properties and capabilities of the MEE or MES related to autonomy [**SOURCE: IEC 60601-4-1(in preparation) 3.7**]
201.3.205 MEDICAL ROBOT	ROBOT intended to be used as a MEE or MES [**SOURCE: IEC 60601-4-1(in preparation) 3.19**]
201.3.208 REHABILITATION, ASSESSMENT, COMPENSATION AND ALLEVIATION ROBOT (RACA ROBOT)	MEDICAL ROBOT intended to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION comprising an ACTUATED APPLIED PART. NOTE 1: MEDICAL ROBOTS that assist or support daily life activities but not through addressing impaired body functions or structures are not included in this definition, for example a robotic wheelchair or a feeding robot
201.3.210 ACTUATED APPLIED PARTS	APPLIED PART that is intended to provide actively controlled forces to the PATIENT related to the PATIENT's MOVEMENT FUNCTIONS needed to perform a CLINICAL FUNCTION of a RACA ROBOT APPLIED PART that is intended to provide actively controlled forces to the PATIENT related to the PATIENT's MOVEMENT FUNCTIONS needed to perform a CLINICAL FUNCTION of a RACA ROBOT

Involvement of more experts is always desirable!

Through your national standardization body, through ISO or IEC.