Ongoing work on safety standardization of rehabilitation robots

ISO TC299 – IEC TC62D
Joint Working Group 36 under JWG 5
Medical Robots for Rehabilitation
MISSION
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/
FDA is giving clearance to these devices for home use at this point (ReWalk, Parker Indego)
The diagram illustrates the hierarchy of standards organizations with "International" at the top, "Regional" in the middle, and "National" at the bottom. Key organizations include:

- **IEC/ISO** (International)
- **CENELEC** (Europe)
- **COPANT** (Panamericans)
- **CANENA** (Mexico Canada USA)
- **DKE** (Germany)
- **BSI** (England)
- **ANSI** (USA) and **AAMI** (USA)
- **CSA** (Canada)
- **JIS** (Japan)
- **GB** (China)
- **VDE** (Germany DIN)
- **ZVEI** (Germany)
- **VIK** (Germany)
- **IEEE** (England)
- **NEMA** (USA)
- **IEEE** (USA)
- **UL** (USA)
- **...**

The pyramid structure shows the flow from public to private standards, with international standards at the top and national standards at the bottom.
IEC 60601 – Safety of Medical Devices

ISO TC 299 Robots and Robotic Devices

= 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

<table>
<thead>
<tr>
<th>Table 1 – Project stages and associated documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project stage</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>Preliminary stage</td>
</tr>
<tr>
<td>Proposal stage</td>
</tr>
<tr>
<td>Preparatory stage</td>
</tr>
<tr>
<td>Committee stage</td>
</tr>
<tr>
<td>Enquiry stage</td>
</tr>
<tr>
<td>Approval stage</td>
</tr>
<tr>
<td>Publication stage</td>
</tr>
</tbody>
</table>

Legend:
- These stages may be omitted, as described in Annex F.
- Draft International Standard in ISO, committee draft for vote in IEC.
- May be omitted (see 2.6.4).

Status
29 International Members
CDM Committee Draft;
24 Month Schedule

Last Meeting: January 2016
Arlington; DC; USA (AAMI)
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 Rehabilitation 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
<table>
<thead>
<tr>
<th>Defined terms</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>201.3.204 DEGREE OF AUTONOMY</td>
<td>Taxonomy based on the properties and capabilities of the MEE or MES related to autonomy [SOURCE: IEC 60601-4-1(in preparation) 3.7]</td>
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<tr>
<td>201.3.205 MEDICAL ROBOT</td>
<td>ROBOT intended to be used as a MEE or MES [SOURCE: IEC 60601-4-1(in preparation) 3.19]</td>
</tr>
<tr>
<td>201.3.208 REHABILITATION, ASSESSMENT, COMPENSATION AND ALLEVIGATION ROBOT</td>
<td>MEDICAL ROBOT intended to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIGATION 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</td>
</tr>
<tr>
<td>201.3.210 ACTUATED APPLIED PARTS</td>
<td>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</td>
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</tbody>
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Involvement of more experts is always desirable!

Through your national standardization body, through ISO or IEC.