Standards Activity for Powered Exoskeletons

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IEC Joint Working Group 36

- Organizational Structure: TC 62/SC 62D/ JWG 36
  - TC 62 Electrical equipment in medical practice
  - SC 62D Electromedical equipment
  - JWG 36 Medical Robots for Rehabilitation

**JWG 36 Scope:** To develop IEC 80601-2-78: Medical Electrical Equipment - Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, compensation or alleviation of disease, injury or disability
Who is involved in JWG 36?

• Chair: Jürgen Stettin (DE) – IEC SC 62D
• Secretary: Jeffrey Eggleston (US) – IEC SC 62D
• Convenor: Michel Brossoit (CA) - CSA
• Project Lead: Burkhard Zimmermann (CH) - Hocoma AG, IISART
Who else is involved in JWG 36?

• Industry representatives
  – International companies with expertise or interest in medical robotics

• Regulatory agency representatives
  – Officially, just the FDA but...
    • Participants from PMDA (Japanese FDA)
    • KFDA (Korean FDA) informed by Korean experts in JWG36

• Standards agency representatives
  – ISO, IEC, AAMI
Development of IEC 80601-78

• Currently a draft standard
• Committee Draft (CD1) should be finalized after next meeting in February
• Commenting Period
  – Should be mid 2017
  – Will last around 2 months
• If comments are extensive, CD2 may be necessary
Why is this Standard Important?

• Global harmonization on a device area with no current standards

• Device-specific safety considerations which may not be covered elsewhere

• Helps build consistency and avoid common design flaws
  – Helps limit avoidable adverse events

• If recognized by FDA, may lead to reduced burdens on Industry and FDA Staff

• Adapt to new technologies in the future with updates
What does IEC 80601-78 cover?

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.

Excluded:
• Robotic (external limb) prosthetics
• Diagnostic imaging equipment
• Robots that don’t address impaired body structures or functions
What does IEC 80601-78 include?

NOTE: Content has not been finalized and may change.

• Defines “RACA ROBOT”
  – MEDICAL ROBOT intended to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION comprising an ACTUATED APPLIED PART

• Amends and/or adds RACA ROBOT-specific considerations to IEC 60601-1 clauses.

• May introduce concept of SITUATION AWARENESS
FDA Staff Contacts for JWG 36

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Discussion Questions

• **Terminology:** What terms are associated with medical exoskeletons, their testing, manufacturing processes, and use?

• **Taxonomy:** Are there subgroup classification categories that should be considered for a medical exoskeleton standard?

• **Use Cases/Applications:** What are the potential applications for medical exoskeletons and where can these devices be used?
Discussion Questions

• Metrics:
  – What metrics should be used to evaluate the device performance?
  – What measures can be used in standards to assess user safety?

• Measurement Tools
  – What tools exist/don’t exist that are/would be useful to measure the safety and performance of exoskeletons?

• Test Methods: What are the key areas of non-clinical testing that can be addressed by standards?
  – What testing methods can be used to characterize device performance? Device safety?
  – What are the scientific and clinical considerations for testing of atypical structures (e.g. soft fabric based exoskeletons)?
  – Should the standard include cybersecurity testing and usability?

• Stakeholders
  – Who are the stakeholders for these exoskeletons?