

Standards Activity for Powered Exoskeletons

Eric Franca, Ph.D.
Lead Reviewer/Biomedical Engineer
CDRH/ODE/DNPMD/NSDP
and
Primary Liaison and Member of JWG36

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

Eric Franca, PhD

Biomedical Engineer, Primary Liaison and Member of JWG36

DNPMD/NSDP

Eric.Franca@fda.hhs.gov

Ian Marcus, MS

Biomedical Engineer and Alternate Liaison for JWG36

DNPMD/PMDB

Ian.Marcus@fda.hhs.gov



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?

