

IEC 80601-2-78 Ed.1

Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

< Overview >

IEC 80601-2-78 Ed.1 is a particular standard in the IEC 60601 SERIES for medical robots for rehabilitation of patient's movement functions and so on. Japan is the convenor of the Joint Working Group developing this standard.

< Technical Committee >

Joint Working Group 36 (JWG36) of IEC/SC 62D and ISO/TC 299

< Main Points >

The scope of this standard applies to medical robots that physically interact with patients with an impairment to provide recovery of functions, as shown below:

- Rehabilitation: Treatment to improve movement functions.
- Assessment: Procedure to quantify or to aid in the qualification of the level of impairment of a patient.
- Compensation: Mitigation of impairment of a patient through support or replacement of body functions.
- Alleviation: Treatment to ease symptoms due to an impairment of a patient.

< Publication History >

- In 2015, Joint Working Group 36 (JWG36) of IEC/SC 62D and ISO/TC 299 was established, and the development of a safety standard for rehabilitation-type robots was initiated.
- The Committee Draft (CD) document was completed at the 2017 meeting in Busan, and a call for comments was made.
- At the Augsburg meeting in April 2018, comments on the CDV (Committee Draft for Vote) document were addressed, and discussions for creating the FDIS (Final Draft International Standard) document were held at the Kyoto meeting in June.

< PMDA Involvement >

Attendance at international conferences, teleconferences, and domestic committee meetings.