

IEC 60601 Ed.4 Design Specification  
Design Specification Outline for the fourth edition of IEC 60601-1

< Overview >

IEC 60601-1 Ed.4 Design Specification supplements the Architectural Specification and provides clear, concise basis for developing the next edition of IEC 60601-1. The content and specific requirements are grouped into general requirements and a set of clusters according to kind or source of harm/hazardous situation

< Technical Committee >

IEC/TC 62 ad-hoc group 2 (AG2)

< Main Points >

- This document is intended to provide information to develop a user-friendly, distinct and easily readable edition of IEC 60601-1. It provides the philosophy, principles in drafting the fourth edition as well as how the proposed grouping of the work will be performed.
- It is the intention of the 4<sup>th</sup> edition to include the requirements of the general standard and collateral standards (as well as some “general” particular standards) into one document.
- All technical requirements related to specific hazards (e.g., electrical, mechanical, electromagnetic, radiation) are grouped into separate clusters.
  - A. General requirements
  - B. Physical environment hazards
  - C. User interface aspects (including all labelling and information to be provided)
  - D. Materials hazards
  - E. PEMS (e.g., SaMD (Software as a medical device), SiMD (Software in a medical device), firmware, software, apps, OS, drivers) related hazards
  - F. Electrical hazards
  - G. Mechanical hazards
  - H. Thermal and fire hazards
  - I. Optical radiation (visible, UV and IR) hazards
  - J. Ionizing radiation hazards
  - K. Electromagnetic radiation (not optical or ionizing but including SAR) hazards
  - L. Electromagnetic disturbances (including coexistence) hazards

#### <Publication History>

- Based on the deliberations of the IEC SC 62A plenary meeting in 2022, a draft Design Specification was circulated as Document for Comments to IEC TC 62 and its subcommittee and relevant organizations.
- The draft Design Specification reflecting national comments was circulated as a questionnaire in 2023 and approved by the IEC TC 62 plenary meeting and the SC 62A plenary meeting in 2023.
- It was published on the website as a Supporting Document of IEC SC 62A in January 2024.

#### <PMDA Involvement >

Attendance at domestic committees.