

IEC 60601-1 – THE THIRD EDITION

By Charles Sidebottom, Harvey Rudolph, Michael Schmidt and Leo Eisner

IEC 60601-1:2005 (first edition)
published in 2007

The third edition of IEC 60601-1 represents a major overhaul of the IEC 60601 family of medical electrical equipment safety standards. First published in 1977, IEC 60601-1 has become the 'bible' of electromedical equipment safety and the parent standard of over 60 particular device standards ranging from diagnostic electrocardiographs to electron accelerators used in radiotherapy.

An Outline of the Changes

The journey toward the third edition began before the last amendment was published in 1995. Formal work on the project began in early 1997 and has taken nearly nine years to complete. During the process of developing the third edition, the scope of IEC 60601-1 was significantly modified and expanded. The first major change came when the long-standing debate within IEC Subcommittee 62A over what some considered an unnecessary limitation in the scope of the standard was resolved, and the Subcommittee removed the phrase 'under medical supervision' from the definition of medical electrical equipment. This change ended the debate over whether or not equipment that met all the other characteristics of medical electrical equipment, but was not intended to be used by or under the direct supervision of a trained professional, was within the scope of IEC 60601-1. The automatic external defibrillator (AED) now is covered in airports and other public spaces is a good example. While such devices clearly fulfil all the other characteristics of medical electrical equipment, it can be persuasively argued that they are not intended to be used under medical supervision. Under the revised scope of the third edition, there is no question that AEDs are covered by IEC 60601-1.

The second major change occurred when Subcommittee 62A accepted a proposal from France to add 'or compensation or alleviation of disease, injury or disability' to the definition of medical electrical equipment. Historically, medical electrical equipment was limited to devices intended by their manufacturer to 'diagnose, treat or monitor a patient'. The UK also argued that a strict interpretation of the scope of the second edition of IEC 60601-1 excluded certain patient handling and support equipment. This equipment is not covered in the scope of the IEC Committee dealing with aids for the disabled, except that some models may be intended for both domains of use. Many in the community felt that excluding these devices leaves a large hole in the standard's coverage. A number of other standards, such as ISO 8535 for patient lifting equipment, refer to IEC 60601-1 for electrical safety requirements and so for IEC 60601-1 to exclude this equipment is a contradiction.

Another issue that was extensively debated during the development of the third edition was the relationship of the collateral

Changes of the standard
have been discussed and
explained in detail within

Definition of medical
electrical equipment
now extended

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