

IEC 60601-1 3rd Ed., 2nd Amendment

An Overview

Total Quality Assurance in Medical Electrical Equipment

Stay ahead of the curve. Intertek has the solutions and expertise to ensure you are prepared for the latest standard developments for medical electrical equipment. Amendment 2 to IEC 60601-1 Ed. 3 is expected to be published in August 2020.



IEC 60601-1 Edition 3 - The need for further changes

The publication of IEC 60601-1 Edition 3 (2012) allowed equipment designers to meet enhanced performance requirements required for new medical technologies addressing "smart care".

Continuing technology and medical care "smart care" will continue to drive changes to the original standard. Amendment 2 to the original standard is necessary to keep pace with the latest medical care, such as the use of telemedicine, remote patient monitoring and surgical device interfaces.

As technology continues to evolve, a "smart" system requires the user and system to adapt and evolve. These new requirements, along with the growing need for interoperability, are driving the need for a new standard. The system for a new standard is being developed by IEC 60601-1, which will be published in August 2020.

Amendment 2 to IEC 60601-1 Edition 3 (2012) will be published in August 2020.

IEC 60601-1 Edition 3 (2012) will be published in August 2020. The standard will be published in August 2020. The standard will be published in August 2020.

The key difference of Amendment 2 with respect to product designs

Amendment 2 introduces further design requirements for the product designer, covering electromagnetic compatibility and safety requirements for the product designer.

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- Electromagnetic compatibility (EMC) requirements for the product designer.
- Safety requirements for the product designer.
- Performance requirements for the product designer.
- Environmental requirements for the product designer.

IEC 60601-1 Edition 3 (2012)	IEC 60601-1 Edition 3 (2012) Amendment 2 (2020)
IEC 60601-1 Edition 3 (2012) requires the product designer to meet the requirements for the product designer.	IEC 60601-1 Edition 3 (2012) Amendment 2 (2020) requires the product designer to meet the requirements for the product designer.
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Iec 60601 3rd Edition Amendment 1

**International Electrotechnical
Commission**



Iec 60601 3rd Edition Amendment 1:

Practical Radiation Protection in Healthcare Colin J. Martin, David G. Sutton, 2015 Written by practitioners experienced in the field Practical Radiation Protection in Healthcare provides a practical guide for medical physicists and others involved with radiation protection in the healthcare environment

Assessment of the Impact of the Most Significant Changes in Amendment 1 to IEC 60601-1:2005 and Mapping of the Clauses of IEC 60601-1:2005 to the Previous Edition International Electrotechnical Commission, International Electrotechnical Commission. Technical Committee 62, 2012

Amendment 1 to ANSI/AAMI/IEC 60601-1-2:2001, Medical Electrical Equipment, Part 1: General Requirements for Safety. 2. Collateral Standard American National Standards Institute, Association for the Advancement of Medical Instrumentation, 2004-01-01

Medical Electrical Equipment. Guidance and Interpretation. Considerations of Unaddressed Safety Aspects in the Third Edition of IEC 60601-1 and Proposals for New Requirements British Standards Institute Staff, 1915-04-30 Medical equipment Electrical medical equipment Electrical equipment Electronic equipment and components Safety engineering Electrical safety Safety measures Defibrillators Medical instruments Cardiology Heart Monitors

Medical Electrical Equipment, 2015

Medical Electrical Equipment International Electrotechnical Commission, 1988

Medical Electrical Equipment - Part 2-1 Malaysia. Jabatan Standard, 2006

Amendment 1 International Electrotechnical Commission, Canadian Standards Association, 2001

Considerations of Unaddressed Safety Aspects in the Second Edition of IEC 60601-1 and Proposals for New Requirements Association for the Advancement of Medical Instrumentation, 2003-12

Medical Electrical Equipment Malaysia. Jabatan Standard, 2007

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