

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 manufacturers to demonstrate performance requirements for low voltage medical electrical equipment. Some were:

considering the safety and electrical risk "low risk" when submitted for certification. The original intention of Amendment 2 for the original publication (2012) was to bring the standard up to date with the current state of the art in the field of medical electrical equipment. Some of the changes to the standard included:

the introduction of a new section on "Safety" and the addition of a new section on "Electrical safety" and the addition of a new section on "Electrical safety" and the addition of a new section on "Electrical safety". The original intention of Amendment 2 for the original publication (2012) was to bring the standard up to date with the current state of the art in the field of medical electrical equipment. Some of the changes to the standard included:

the introduction of a new section on "Safety" and the addition of a new section on "Electrical safety" and the addition of a new section on "Electrical safety". The original intention of Amendment 2 for the original publication (2012) was to bring the standard up to date with the current state of the art in the field of medical electrical equipment. Some of the changes to the standard included:

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The key difference of Amendment 2 with respect to product designs

Amendment 2 introduced and further clarified requirements of the product safety category, which is a key factor in determining the level of risk for the product. The original intention of Amendment 2 for the original publication (2012) was to bring the standard up to date with the current state of the art in the field of medical electrical equipment. Some of the changes to the standard included:

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Category	Requirements	Test Methods
Category 1	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 2	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 3	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 4	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 5	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 6	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 7	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 8	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 9	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)
Category 10	Low voltage medical electrical equipment	IEC 60601-1 Ed. 3 (2012)

Iec 60601 3rd Edition Amendment 1

Rachel Sandford



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