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## IEC 60601-1-11:2015

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Medical electrical equipment -- Part 1-1 1: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015 applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems for use in the home healthcare environment. It applies regardless of whether the medical electrical equipment or medical electrical system is intended for use by a lay operator or by trained healthcare personnel. The home healthcare environment includes:

- the dwelling place in which a patient lives;
- other places where patients are present both indoors and outdoors, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present. This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision. The most significant changes with respect to the previous edition include the following modifications:
- correction of test method for relative humidity control at temperatures above 35 °C;
- redrafting of subclauses that altered instead of adding to the general standard or other collateral

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**Format** **Language**



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standards; and

- harmonizing with the changes to the amendments to the general standard and other collateral standards.

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## Life cycle

A standard is reviewed every 5 years

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## Revisions / Corrigenda

**Previously**

- ⊗ IEC 60601-1-11:2010
- ⊗ IEC 60601-1-11:2010/Cor 1:2011

**Now under review**

- ⊗ IEC 60601-1-11:2015

**Corrigenda/Amendments**

- ⊗ IEC 60601-1-11:2015/CD Amd 1

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