

## CLC/TC 62 Electrical equipment in medical practice

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### Project

<b>Reference</b>	EN 60601-1-2:2014
<b>Title</b>	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
<b>Project Number</b>	24111
<b>Abstract/Scope</b>	IEC 60601-1-2:2014 applies to the basic safety and essential performance of Medical Equipment (ME) equipment and ME systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by me equipment and me systems. This collateral standard to IEC 60601-1 specifies general requirements and tests for basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions of ME equipment and ME systems. They are in addition to the requirements of the general standard IEC 60601-1 and serve as the basis for particular standards. This fourth edition cancels and replaces the third edition of IEC 60601-1-2, and constitutes a technical revision. The most significant changes with respect to the previous edition include the following modifications: - specification of immunity test levels according to the environments of intended use, categorized according to locations that are harmonized with IEC 60601-1-11: the professional healthcare facility environment, the home healthcare environment and special environments; - specification of tests and test levels to improve the safety of medical electrical equipment and medical electrical systems when portable RF communications equipment is used closer to the medical electrical equipment than was recommended based on the immunity test levels that were specified in the third edition; - specification of immunity tests and immunity test levels according to the ports of the medical electrical equipment or medical electrical system; - specification of immunity test levels based on the reasonably foreseeable maximum level of electromagnetic disturbances in the environments of intended use, resulting in some immunity test levels that are higher than in the previous edition; and - better harmonization with the risk concepts of basic safety and essential performance, including deletion of the defined term 'life-supporting'. This new edition includes the following main additions: - guidance for determination of immunity test levels for special environments; - guidance for adjustment of immunity test levels when special considerations of mitigations or intended use are applicable; - guidance on risk management for basic safety and essential performance with regard to electromagnetic disturbances; and - guidance on identification of immunity pass/fail criteria.
<b>Status</b>	Approved

### Status

<b>Current Stage code</b>	60.55.0000
<b>Current Stage code date</b>	2014-04-01
<b>Current Stage code deadline</b>	2014-06-02
<b>Target date for vote</b>	2013-11-26
<b>Legal</b>	
<b>Directive(s)</b>	2004/108/EC, 93/42/EEC
<b>Mandate(s)</b>	M/295
<b>Order Voucher</b>	

### Implementation Dates

<b>date of Ratification (DOR) (1)</b>	2014-04-01
<b>date of Availability (DAV) (2)</b>	-
<b>date of Announcement (DOA) (3)</b>	2014-07-01
<b>date of Publication (DOP) (4)</b>	2015-01-01
<b>date of Withdrawal (DOW) (5)</b>	2018-12-31

### Relations

<b>Supersedes</b>	<a href="#">EN 60601-1-2:2007</a> <a href="#">EN 60601-1-2:2007/corrigendum Mar. 2010</a>
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### Superseded by

- (1) Date of ratification (dor) date when the Technical Board notes the approval of an EN (and HD for CENELEC), from which time the standard may be said to be approved
- (2) Date of availability (dav) date when the definitive text in the official language versions of an approved CEN/CENELEC publication is distributed by the Central Secretariat
- (3) Date of announcement (doa) latest date by which the existence of an EN (and HD for CENELEC), a TS or a CWA has to be announced at national level
- (4) Date of publication (dop) latest date by which an EN has to be implemented at national level by publication of an identical national standard or by endorsement
- (5) Date of withdrawal (dow) latest date by which national standards conflicting with an EN (and HD for CENELEC) have to be withdrawn
- (6) This list of normative references is purely indicative. The only official list of normative references is the list of the published standard.

In the case of undated standard, a link to the last dated version is provided.

In the case of series, a link to each standard identified in the series is provided.

We also invite you to check (via the website) whether corrigenda and/or amendments shall be read in conjunction with the main standard.