



BSI Standards Publication

Medical electrical equipment

Part 4-3: Guidance and interpretation — Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements

National foreword

This Published Document is the UK implementation of IEC TR 60601-4-3:2018. It supersedes PD IEC/TR 60601-4-3:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

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TECHNICAL REPORT



**Medical electrical equipment –
Part 4-3: Guidance and interpretation – Considerations of unaddressed safety
aspects in the third edition of IEC 60601-1 and proposals for new requirements**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 4-3: Guidance and interpretation – Considerations
of unaddressed safety aspects in the third edition of IEC 60601-1
and proposals for new requirements**

FOREWORD

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IEC TR 60601-4-3, which is a technical report, has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-4-3 published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition: addition of 47 new recommendations.

The text of this document is based on the following documents:

Enquiry draft	Report on voting
62A/1236/DTR	62A/1258A/RVDTR

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

Terms used throughout this document that have been defined in Clause 3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014 are printed in SMALL CAPITALS.

A list of all parts in the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this document may be issued at a later date.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

At the Sydney meeting in November 1993, IEC subcommittee (SC) 62A established a procedure under which working group (WG) 14 would develop recommendations regarding problems of interpretation or application of IEC 60601-1. WG 14 is made up of experts with particular expertise in testing according to the requirements of IEC 60601-1. Many of the experts on WG 14 are employed by test laboratories with a long history of applying IEC 60601-1 to MEDICAL ELECTRICAL EQUIPMENT. While the National Committee members of SC 62A nominate these experts, their recommendations were not to be formally adopted through any official voting procedure. To reinforce this process, the subcommittee specifically directed that the following note appear on every page of the resulting informational circular:

IMPORTANT NOTE: Per the 62A decision at Sydney (see RM3755/SC62A, August 1993), the 62A Secretary is circulating this recommendation, prepared by 62A/WG 14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NCs.

This recommendation/interpretation is the result of considerations by a group of nominated experts and has not been formally adopted through any National Committee voting procedure. Distribution is only for information.

At the November 2000 meeting of SC 62A in Tokyo, the subcommittee discussed ways and means for achieving a wider distribution of the WG 14 recommendations. At the conclusion of this discussion, the subcommittee instructed the Secretariat to develop a technical report (TR) based on the published recommendations of WG 14. This technical report is intended to convey the results of WG 14's work to interested parties such as MANUFACTURERS and test laboratories while retaining the informative nature of the manual.

This second edition of IEC TR 60601-4-3 contains 143 recommendations, numbered 101 to 243. All these recommendations are based upon IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014.

The numbering starts with 101 instead of just 1 to ensure that these WG 14 recommendations (101 to 243) will not accidentally be confused with previously issued WG 14 recommendations 1 to 63, which are based on IEC 60601-1:1998 and published in IEC TR 62296:2009.

This document may be amended from time to time as WG 14 prepares additional recommendations.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-3: Guidance and interpretation – Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements

1 Scope

This part of IEC 60601, which is a Technical Report, contains a series of recommendations developed by an expert working group of IEC subcommittee 62A in response to questions of interpretation of IEC 60601-1:2005 and related collateral standards in the IEC 60601 series.

This document is primarily intended to be used by:

- MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT;
- test laboratories and others responsible for assessment of compliance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014;
- those developing subsequent editions of IEC 60601-1.

The recommendations in the first edition of IEC TR 62296 were considered in preparing the third edition of IEC 60601-1. Similarly, it is expected that these recommendations within IEC 60601-4-3 will be considered when preparing future revisions of IEC 60601-1 and related collateral standards in the IEC 60601 series.

The object of this document is to make the recommendations/interpretations available to those interested in the application of the third edition of IEC 60601-1 and applicable collateral standards.

NOTE There might be other acceptable solutions which are not reflected in this document. The reader is reminded that, although a majority of the National Committee members of IEC/SC 62A have approved publication of this document, the contents remain the opinion of the expert members having participated in the drafting of the document. These recommendations/interpretations are the result of considerations by this group of nominated experts and have not been formally adopted through any National Committee voting procedure. Distribution is only for information.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE For improved reading and easy understanding of the recommendation section of each issue, the referenced standards are written as follows:

- a) Written IEC 60601-1:2005, meant only Edition 3.0 from 2005.
- b) Written IEC 60601-1:2005/AMD1:2012, meant only Amendment 1:2012.
- c) Written IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, meant Edition 3.0 and Amendment 1:2012 combined.
- d) Written IEC 60601-1 (in undated form), meant IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (in the year 2018 the latest edition of IEC 60601-1).

If an edition is not explicitly specified, all editions referenced in this normative references clause applies.