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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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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.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/951/DTR	62A/973A/RVC

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

Terms used throughout this technical report that have been defined in Clause 3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012 are printed in SMALL CAPITALS.

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

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- withdrawn,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

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

INTRODUCTION

At the Sydney meeting in August 1994, 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 1994), 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 material.

This first edition of IEC TR 60601-4-3 contains 93 recommendations, numbered 101 to 193. All these recommendations are based upon IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

The numbering starts with 101 instead of just 1 to ensure that these WG 14 recommendations (101 to 193) will not accidentally be confused with previous issued WG 14 recommendations 1 to 63, which are based on the second edition of IEC 60601-1 and published in IEC TR 62296.

This technical report 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 and object

1.1 Scope

This technical report contains a series of recommendations developed by an expert working group of IEC subcommittee 62A in response to questions of interpretation of the third edition of IEC 60601-1.

This technical report 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 and IEC 60601-1:2005/AMD1:2012, and

– 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 a future revision of IEC 60601-1.

1.2 Object

The object of this technical report is to make the recommendations/interpretations developed by the experts in IEC/SC 62A/WG 14 available to those interested in the application of the third edition of IEC 60601-1.

The reader is reminded that, although a majority of the National Committee members of IEC/SC 62A have approved publication of this technical report, the contents remain the opinion of the expert members of WG 14. 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: 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*