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TECHNICAL REPORT

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Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ASSESSMENT OF THE IMPACT OF THE MOST SIGNIFICANT CHANGES IN AMENDMENT 1 TO IEC 60601-1:2005 AND MAPPING OF THE CLAUSES OF IEC 60601-1:2005 TO THE PREVIOUS EDITION

FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 62348, 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 published in 2006. The second edition retains the mapping that traces the requirements of IEC 60601-1:2005 and its Amendment A1:2012 (Edition 3.1) from their source in the documents that relate to IEC 60601-1:1998 and its amendments (Edition 2.2). See Clause 7. The second edition adds an assessment of the impact of the most significant changes in Amendment 1:2012 (Clauses 4, 5 and 6).

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

Enquiry draft	Report on voting
62A/831/DTR	62A/841/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.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site 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- withdrawn,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.

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

The first edition of this technical report was created by the Secretariat of SC 62A to assist users of IEC 60601-1 by providing a tool to trace requirements between IEC 60601-1:2005 and their source in the documents that form the basis of the third edition; principally the second edition as amended.

At the Auckland meeting in 2008, IEC Technical Committee (TC) 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

– those issues reported to the Secretariat of IEC Subcommittee (SC) 62A since the publication of IEC 60601-1:2005;

– the way in which risk management has been introduced into IEC 60601-1:2005; and

– the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the Secretariat of SC 62A has received 73 additional issues from National Committees or other interested parties for a total of 182 identified issues with the 2005 edition. Amendment 1 to IEC 60601-1:2005 is intended to address those issues.

The amendment process has resulted in 496 separate changes. Each change was assessed by the experts developing the amendment for its potential impact on users of the standard. Most of the changes are editorial corrections or clarifications and were assessed as having minimal or no impact on the application of the standard. Others were assessed as having moderate or significant impact because they represent a technical change, or they impact a wide range of users, or both.

The second edition of this technical report was prepared by the Secretariat of IEC/SC 62A to summarize those changes that were assessed during the development process as having a moderate to significant impact on users of IEC 60601-1.

The tables from the first edition of this technical report were retained in the second edition because there are counties that have not fully transitioned to the third edition of IEC 60601-1. Therefore, the original contents of IEC/TR 62348 remain useful in those countries.

Table 6 has been updated to include new subclauses added in Amendment 1:2012 (highlighted in blue).

ASSESSMENT OF THE IMPACT OF THE MOST SIGNIFICANT CHANGES IN AMENDMENT 1 TO IEC 60601-1:2005 AND MAPPING OF THE CLAUSES OF IEC 60601-1:2005 TO THE PREVIOUS EDITION

1 Scope

This technical report provides a tool to assist users of IEC 60601-1:2005 to assess the impact of the most significant changes in Amendment 1:2012.

This technical report also provides a tool to assist users of IEC 60601-1 to trace requirements between the third edition and their source in the documents that form the basis of the third edition; principally the second edition as amended.

This report is intended to be used by:

– those who must align standards based on the second edition of IEC 60601-1 with the third edition as amended;

– manufacturers of medical electrical equipment or medical electrical systems;

– health care regulatory authorities, test houses and other organizations responsible for implementing standards for medical electrical equipment and medical electrical systems.

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*
Amendment 1:2012