IEC/TR 62348

Edition 2.0 2012-12

TECHNICAL REPORT

colour inside

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

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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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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- withdrawn,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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 + A1:2012 apply.

4 Assessment of the changes in Amendment 1:2012

Amendment 1 contains 496 separate changes. During the development of the amendment, each change was assessed by the experts involved for its potential impact on users of the standard. Most of the changes are editorial corrections or clarifications and were assessed and having minimal or no impact on the application of the standard.

However, 83 of the changes were assessed as having a moderate to significant impact on the users of the standard. This assessment is based on the likelihood that some alterations to the design documentation, testing, the product itself or its accompanying documents will be required because of the change to a requirement in the amendment.

The changes have been divided into two groups:

– those assessed as having a significant impact (Table 1), and

– those assessed as having a moderate impact (Table 2).

Because any assessment is somewhat subjective, users of the standard are encouraged to review the contents of the amendment and determine its impact on the sections that are relevant to their products.

Table 1 – Amendment 1 changes assessed as having the potential for a significant impact

Clause of IEC 60601-1	Clause Title	Impact many users	Impact particular users	Section of this document
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	X		5.3
4.3	Essential performance	X		5.4
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	X		5.5
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	X		5.6
5.1	TYPE TESTS	X		5.8
5.5 a)	Supply voltages, type of current, nature of supply, frequency	X		5.9
5.7	Humidity preconditioning treatment	X		5.10
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts	X		5.13
7.2.4	ACCESSORIES	X		5.13
7.2.5	ME EQUIPMENT intended to receive power from other equipment		X	6.1
7.2.21	Mass of MOBILE ME EQUIPMENT		X	6.4
7.9.1	General	X		5.17
7.9.3.1	General	X		5.20
8.5.5.1 a)	Defibrillation protection		X	6.7
8.5.5.2	Energy reduction test		X	6.8
8.7.3	Allowable values	X		5.24
8.8.1	General	X		5.26
9.2.3.1	Unintended movement		X	6.14
9.4.2.3 a)	Instability from horizontal and vertical forces		X	6.16
9.4.2.4.3	Movement over a threshold		X	6.17
9.4.3.2 b)	Instability excluding transport position		X	6.20
10.3	Microwave radiation		X	6.27
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	X		5.31
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		X	5.32
15.5.3	Construction of transformers used to provide separation as required by 8.5	X		5.42

Table 2 – Amendment 1 changes assessed as having the potential for a moderate impact *(1 of 2)*

Clause of IEC 60601-1	Clause Title	Impact many users	Impact particular users	Section of this document
2	Normative references	X		5.1
3.28	EXPECTED SERVICE LIFE	X		5.2
4.11	Power input	X		5.7
5.9.2.3	Actuating mechanisms	X		5.11
7.1.2	Legibility of markings	X		5.12
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES	X		5.14
7.2.17	Protective packaging		X	6.2
7.2.18	External pressure source		X	6.3
7.4.2	Control devices	X		5.15
7.5	Safety signs	X		5.16
7.9.2.1	General		X	6.5
7.9.2.15	Environmental protection	X		5.18
7.9.2.17	ME EQUIPMENT emitting radiation		X	6.6
7.9.2.18	ME EQUIPMENT and ACCESSORIES supplied sterile		X	6.2
7.9.2.19	Unique version identifier	X		5.19
7.9.3.1	General	X		5.19
8.1 b)	Fundamental rule of protection against electric shock	X		5.21
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)	X		5.22
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	X		5.22
8.6.4	Impedance and current-carrying capability	X		5.23
8.7.1 b)	General requirements		X	6.9
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection	X		5.25
Table 16	Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION	X		5.27
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	X		5.28
8.11.1	Isolation from the SUPPLY MAINS		X	6.10
9.2.2.4.4	Other RISK CONTROL measures		X	6.11
9.2.2.5	Continuous activation		X	6.12
9.2.2.6	Speed of movement(s)		X	6.13
9.2.3.2	Overtravel end stops		X	6.15
9.4.3.1 c)	Instability in transport position		X	6.18
9.4.3.2 a)	Instability excluding transport position		X	6.19
9.6.1	General		X	6.21
9.6.2.1	Audible acoustic energy		X	6.22
9.8.3.2	Static forces due to loading from persons		X	6.23
9.8.3.3	Dynamic forces due to loading from persons		X	6.24
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation		X	6.25

Table 2 *(2 of 2)*

Subclause of IEC 60601-1	Clause Title	Impact many users	Impact particular users	Section of this document
10.1.2	ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation		X	6.26
10.4	Lasers		X	6.28
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT		X	6.29
11.6.2	Overflow in ME EQUIPMENT		X	6.30
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEMS	X		5.29
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS	X		5.30
12.4.5.2	Diagnostic X-ray equipment		X	6.31
14.1	General	X		5.33
14.9	Design and implementation	X		5.34
14.11	PEMS VALIDATION	X		5.35
14.13	PEMS intended to be incorporated into an IT-NETWORK		X	6.32
15.3.1	General	X		5.36
15.3.5	Rough handling test		X	6.33
15.4.2.1 d)	Application		X	6.34
14.4.3.5	Excessive current and voltage protection		X	6.35
15.4.6.1 b)	Fixing, prevention of maladjustment	X		5.37
15.4.6.2	Limitation of movement	X		5.38
15.4.7.3	Entry of liquids		X	6.36
15.5.1.1	Transformers	X		5.39
15.5.1.3	Overload test	X		5.40
15.5.2	Dielectric strength	X		5.41
16.3	Power supply		X	6.37
16.6.4.1	General conditions for ME SYSTEMS		X	6.38
16.8	Interruption of the power supply to parts of an ME SYSTEM		X	5.31
16.9.2.1 d)	MULTIPLE SOCKET-OUTLET		X	6.39
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS		X	6.40
Annex A, 4.8	Components of ME EQUIPMENT	X		5.43

The following clauses break down the changes into two groups based on the breadth of their anticipated impact.

– The first group are those changes that are anticipated to impact many, if not most, of the users of IEC 60601-1 (Clause 5). An example would be the change to the requirements for humidity preconditions testing to align with the IEC Certified Testing Laboratories (CTL) decision to harmonize basic environmental testing conditions for electrical products. Because of the impact on existing test protocols, the impact was assessed as significant.

– The second group are those changes that should impact only some of the users of IEC 60601-1 depending on the nature of the equipment to which they are applying the standard (Clause 6). Examples are the requirements that are applied only to sterile ME EQUIPMENT or ME EQUIPMENT parts or to MOBILE ME EQUIPMENT.

5 Changes impacting many users of the standard

5.1 Updated normative references (Clause 2) [Moderate impact]

A number of the standards that are referenced in the 3rd edition have been revised or have been withdrawn and replaced by different documents (e.g., ISO 14971-1:2000 has been replaced by ISO 14971:2007). These normative references have been updated to reflect current editions.

5.2 Definition and rationale for EXPECTED SERVICE LIFE (Definition 3.28 and rationale for 4.4) [Moderate impact]

The application of the term EXPECTED SERVICE LIFE has lead to a misunderstanding in some quarters. To address the misunderstanding, the definition and the rationale have been expanded.

5.3 Restructuring of RISK MANAGEMENT (Subclause 4.2) [Significant impact]

Subclause 4.2 and its rationale have been significantly modified and expanded. The subclause describes in greater detail the RISK MANAGEMENT PROCESS to be employed in complying with IEC 60601-1.

Subclause 4.2.1 introduces the concepts and the purposes of RISK MANAGEMENT within the framework of a TYPE TEST or design assurance standard. The subclause includes a reminder that, "*verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS.*"

Subclause 4.2.2 is the heart of the subclause and sets out the basic PROCESS requirements, which remain in compliance with ISO 14971 except for the requirements related to product and post-production monitoring and periodic reviews of the suitability of the RISK MANAGEMENT PROCESS.

Subclause 4.2.3 details how the requirements of this standard are to be applied when evaluating RISK. There are four scenarios described. They are:

a) where IEC 60601-1 or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria;

b) where IEC 60601-1 or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria;

c) where IEC 60601-1 or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements; and

d) where HAZARDS or HAZARDOUS SITUATIONS are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this IEC 60601-1 or its collateral or particular standards.

5.4 Application of ESSENTIAL PERFORMANCE (Subclause 4.3) [Significant impact]

The definition of ESSENTIAL PERFORMANCE has been modified from:

> performance necessary to achieve freedom from unacceptable risk

in the 3rd edition to: