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TECHNICAL REPORT

**Considerations of unaddressed safety aspects in the second edition of
IEC 60601-1 and proposals for new requirements**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

CONSIDERATIONS OF UNADDRESSED SAFETY ASPECTS IN THE SECOND EDITION OF IEC 60601-1 AND PROPOSALS FOR NEW REQUIREMENTS

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 62296, 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 2003. It constitutes a technical revision. This edition includes seven new recommendations: Recommendations 57 through 63. As the third edition of IEC 60601-1 has been published, some of the recommendations in this edition have been changed to align with requirements in IEC 60601-1:2005.

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

Enquiry draft	Report on voting
62A/621/DTR	62A/632/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 maintenance result 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- withdrawn;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.

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 houses 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/WG14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NC's.

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

The plan approved in Sydney called for the 62A Secretary to circulate these recommendations to the member National Committees via an informational (INF) document.

While the quality of the technical work of WG 14 is widely recognized and applauded, the overall process has achieved less than originally hoped. The INF documents have not proved a particularly successful way of getting this information to those who could use it most. The WG 14 recommendations are largely unknown beyond the people actively involved in the work of SC 62A. Several alternatives have been explored. These include making the individual recommendation sheets available on the Internet either through the IEC Web Site, the web site of a participating National Committee, or the web site of an interested third party. However, concerns over intellectual property and control of distribution have proved extremely difficult to overcome.

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 houses while retaining the informative nature of the material.

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

CONSIDERATIONS OF UNADDRESSED SAFETY ASPECTS IN THE SECOND 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 second edition of IEC 60601-1.

This technical report is primarily intended to be used by:

- manufacturers of MEDICAL ELECTRICAL EQUIPMENT;
- test houses and others responsible for assessment of compliance with IEC 60601-1:1988, 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. As the third edition of IEC 60601-1 has been published, some of the recommendations in the second edition of IEC/TR 62296 have been changed to align with requirements in IEC 60601-1:2005. Seven additional recommendations have been developed by IEC/SC 62A/WG 14 and are included in this edition of IEC/TR 62296. They are recommendations 57 through 63.