Medical electrical equipment –

Part 1-2:
General requirements for safety –

Collateral standard:
Electromagnetic compatibility –
Requirements and tests

© IEC 2001 — Copyright - all rights reserved

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Electrotechnical Commission

3, rue de Varembé Geneva, Switzerland

Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

PRICE CODE X

For price, see current catalogue
CONTENTS

FOREWORD ....................................................................................................................... 4
INTRODUCTION ................................................................................................................... 6

SECTION ONE – GENERAL

1 Scope and object ........................................................................................................... 8
  1.201 Scope .................................................................................................................. 8
  1.202 Object .................................................................................................................. 8
2 Terminology and definitions ...................................................................................... 8
3 General requirements ................................................................................................. 11
  3.201 General requirements for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT
       and SYSTEMS ...................................................................................................... 11
6 Identification, marking and documents ................................................................. 12

SECTIONS TWO TO FOUR – NOT USED

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

36 ELECTROMAGNETIC COMPATIBILITY ............................................................... 32
  36.201 EMISSIONS ..................................................................................................... 32
  36.202 IMMUNITY ....................................................................................................... 34

SECTIONS SIX TO TEN – NOT USED

Annex AAA (informative) General guidance and rationale.......................................... 48
Annex BBB (informative) Example completion of Tables 201 through 208.................. 72
Annex CCC (informative) Guidance in classification according to CISPR 11............. 84
Annex DDD (informative) Guidance in the application of IEC 60601-1-2 to Particular
       Standards ..................................................................................................... 86
Annex EEE (informative) ELECTROMAGNETIC ENVIRONMENTS ............................... 89
Annex FFF (normative) Normative references ............................................................ 90

Bibliography ................................................................................................................... 92

Figure 201 – Instructions for completing Table 201 for CISPR 11 EQUIPMENT and
       SYSTEMS ............................................................................................................ 20
Figure 202 – Instructions for completing Table 201 for CISPR 14 and CISPR 15
       EQUIPMENT ........................................................................................................ 21
Figure 203 – Instructions for completing Table 202 ....................................................... 23
Figure 204 – Instructions for completing Tables 203 and 205 for LIFE-SUPPORTING
       EQUIPMENT and SYSTEMS ............................................................................... 28
Figure 205 – Instructions for completing Tables 204 and 206 for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Figure AAA.1 – Example of cable arrangement for radiated IMMUNITY test

Figure AAA.2 – Examples showing maximum dimension for an EQUIPMENT with one and with two cables

Table 201 – Guidance and manufacturer’s declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS

Table 202 – Guidance and manufacturer’s declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Table 203 – Guidance and manufacturer’s declaration – electromagnetic immunity – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Table 204 – Guidance and manufacturer’s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Table 205 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Table 207 – Guidance and manufacturer’s declaration – electromagnetic immunity – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS that are specified for use only in a shielded location

Table 208 – Guidance and manufacturer’s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING and are specified for use only in a shielded location

Table 209 – Modulation frequency, PHYSIOLOGICAL SIMULATION FREQUENCY, and OPERATING FREQUENCY

Table 210 – IMMUNITY TEST LEVELS for voltage dips

Table 211 – IMMUNITY TEST LEVEL for voltage interruption

Table BBB.1 – Example (1) of completed Table 201

Table BBB.2 – Example (2) of completed Table 201

Table BBB.3 – Example (3) of completed Table 201

Table BBB.4 – Example of completed Table 202

Table BBB.5 – Example (1) test, IMMUNITY and COMPLIANCE LEVELS

Table BBB.6 – Example of completed Table 203

Table BBB.7 – Example of completed Table 205

Table BBB.8 – Example of completed Table 204

Table BBB.9 – Example of completed Table 206

Table BBB.10 – Example (2) test, IMMUNITY and COMPLIANCE LEVELS

Table BBB.11 – Example of completed Table 207

Table BBB.12 – Example (3) test, IMMUNITY and COMPLIANCE LEVELS

Table BBB.13 – Example of completed Table 208

Table EEE.1 – Electromagnetic environment
FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-1-2 has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-1-2 cancels and replaces the first edition published in 1993 and constitutes a technical revision.

This second edition constitutes a Collateral Standard to IEC 60601-1: Medical electrical equipment – Part 1: General requirements for safety, hereinafter referred to as the General Standard.

The text of this Collateral Standard is based on the following documents:

<table>
<thead>
<tr>
<th>FDIS</th>
<th>Report on voting</th>
</tr>
</thead>
<tbody>
<tr>
<td>62A/336/FDIS</td>
<td>62A/341/RVD</td>
</tr>
</tbody>
</table>

Full information on the voting for the approval of this Collateral Standard can be found in the report on voting indicated in the above table.
In the IEC 60601 series of publications, Collateral Standards specify general requirements for safety applicable to:

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. ELECTROMAGNETIC COMPATIBILITY).

In addition, IEC 60601-1-1 has expanded the scope of the general standard to include MEDICAL ELECTRICAL SYSTEMS. In recognition of that expanded scope, this edition of the EMC Collateral Standard takes into account the fact that the general standard now applies to MEDICAL ELECTRICAL SYSTEMS as well as MEDICAL ELECTRICAL EQUIPMENT and includes EMC requirements that are, in most cases, applicable to all parts of the SYSTEM.

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures that are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this Collateral Standard, the following print types are used:

- requirements, compliance with which can be tested and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: in smaller type;
- test specifications: in italic type;
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD: SMALL CAPITALS.

NOTE Defined terms are not printed in SMALL CAPITALS in Tables 201-208, in the tables in Annex BBB and in statements required to appear in the ACCOMPANYING DOCUMENTS or instructions for use because they are intended for the customer or user, who may not be familiar with the defined terms of IEC 60601 standards.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) in the left margin of a clause or subclause indicates the presence of additional information in Annex AAA.

Annex FFF forms an integral part of this standard.

Annexes AAA, BBB, CCC, DDD, EEE and the Bibliography are for information only.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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

The need for establishing specific ELECTROMAGNETIC COMPATIBILITY standards for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS (referred to as EQUIPMENT and SYSTEMS, respectively, in this Collateral Standard) is well recognized.

In particular, the existence of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

- safety services;
- other EQUIPMENT and SYSTEMS;
- non-medical electrical equipment (e.g. computers);
- telecommunications (e.g. radio/TV, telephone, radio-navigation).

Of even more importance, the existence of ELECTROMAGNETIC IMMUNITY standards is essential to assure safety of EQUIPMENT and SYSTEMS. ELECTROMAGNETIC COMPATIBILITY (see definition 2.204) differs from other aspects of safety covered by IEC 60601-1 because the electromagnetic phenomena exist, with varying degrees of severity, in the normal use environment of all EQUIPMENT and SYSTEMS and by definition the equipment must “perform satisfactorily” within its intended environment in order to establish ELECTROMAGNETIC COMPATIBILITY. This means that the conventional single fault approach to safety is not appropriate for application to ELECTROMAGNETIC COMPATIBILITY standards. The ELECTROMAGNETIC DISTURBANCE environment can be compared to ambient temperature, humidity and atmospheric pressure. EQUIPMENT and SYSTEMS may experience environmental conditions within the expected range at any time, and for extended periods of time. As with atmospheric pressure and humidity, the user of the EQUIPMENT or SYSTEM may not be aware of ambient levels on a continuous basis. The IMMUNITY TEST LEVELS specified in this standard (IEC 60601 TEST LEVELS) represent the range found in the general medical use environment. Therefore, under these conditions, the performance of the EQUIPMENT or SYSTEM would also be expected to be normal.

IEC 60513 states that the distinction between safety and performance standards is often unclear. EQUIPMENT and SYSTEMS are used in the practice of medicine because they provide needed FUNCTIONS. If an EQUIPMENT or SYSTEM does not provide its needed FUNCTION, because of a lack of IMMUNITY to events expected in the normal use environment, this interferes with the practice of medicine and cannot be considered an acceptable situation. Therefore, this second edition of IEC 60601-1-2 departs from the first edition by establishing a minimum baseline of performance in the presence of expected levels of ELECTROMAGNETIC DISTURBANCE.

This second edition recognizes that there is a shared responsibility between manufacturers, customers and users to ensure that EQUIPMENT and SYSTEMS are designed and operated as intended. The EQUIPMENT or SYSTEM manufacturer’s responsibility is to design and manufacture to meet the requirements of this standard and to disclose information to the customer or user so that a compatible ELECTROMAGNETIC ENVIRONMENT can be maintained in order that the EQUIPMENT or SYSTEM will perform as intended.

Because the practice of medicine involves many specialities, there will by necessity be EQUIPMENT and SYSTEMS that are designed to perform a variety of FUNCTIONS. Some FUNCTIONS involve, for example, measurement of signals from a PATIENT that are of very low levels when compared to ELECTROMAGNETIC NOISE levels that can be coupled into EQUIPMENT and SYSTEMS during the ELECTROMAGNETIC IMMUNITY testing specified in this standard. Because of the proven benefits of many such EQUIPMENT and SYSTEMS, this standard allows the IMMUNITY TEST LEVELS to be lowered, provided there is sufficient justification based on physical, technological or physiological limitations. In this case, the manufacturer is required

---

1 In this standard, “or” should be understood to include “and”.
to disclose the levels at which the EQUIPMENT or SYSTEM meets the performance requirements of this standard and to specify the characteristics of the ELECTROMAGNETIC use environment and how this environment is established, in which the EQUIPMENT or SYSTEM will perform as intended.

This standard also recognizes that for certain environments, higher IMMUNITY LEVELS may be required. Research necessary to determine how to identify the environments that may require higher IMMUNITY LEVELS, as well as what the levels should be, is in progress.

Finally, this standard recognizes that for LIFE-SUPPORTING EQUIPMENT and SYSTEMS, higher levels of IMMUNITY are necessary in order to establish a broader safety margin, even for use in the general medical use environment. Therefore, this standard specifies additional requirements for LIFE-SUPPORTING EQUIPMENT and SYSTEMS.

This second edition allows a risk analysis to be used to determine the ESSENTIAL PERFORMANCE and safety of MEDICAL ELECTRICAL EQUIPMENT that must be examined during IMMUNITY testing and whether testing according to this standard is required for non-medical electrical equipment that is combined with MEDICAL ELECTRICAL EQUIPMENT to form a SYSTEM.

This standard is based on existing IEC standards prepared by SC 62A, TC 77 (Electromagnetic compatibility between electrical equipment including networks) and CISPR (International special committee on radio interference).

The ELECTROMAGNETIC COMPATIBILITY requirements specified by this standard are generally applicable to EQUIPMENT and SYSTEMS as described in 1.201. For certain types of EQUIPMENT and SYSTEMS, these requirements may need to be modified by the special requirements of a Particular Standard. Writers of Particular Standards are encouraged to refer to Annex DDD for guidance in the application of this standard.
MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

SECTION ONE – GENERAL

1 Scope and object

1.201 Scope

This standard applies to ELECTROMAGNETIC COMPATIBILITY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereinafter referred to as EQUIPMENT and SYSTEMS, respectively.

1.202 Object

This standard specifies requirements and tests for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and SYSTEMS and serves as the basis of ELECTROMAGNETIC COMPATIBILITY requirements and tests in Particular Standards.