IEC 60601-1-4

Edition 1.1 2000-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems

Appareils électromédicaux –
Partie 1-4: Règles générales de sécurité – Norme collatérale: Systèmes électromédicaux programmables



IEC 60601-1-4:1996+A1:1999

THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2000 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, 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 either IEC or IEC's member National Committee in the country of the requester.
If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.
Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub
The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, withdrawn and replaced publications.
- IEC Just Published: www.iec.ch/online_news/justpub
Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.
- Electropedia: www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.
- Customer Service Centre: www.iec.ch/webstore/custserv
If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:
Email: csc@iec.ch
Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm
Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,…). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.
- Just Published CEI: www.iec.ch/online_news/justpub
Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.
- Electropedia: www.electropedia.org
Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.
- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:
Email: csc@iec.ch
Tél.: +41 22 919 02 11
Fax: +41 22 919 03 00

IEC 60601-1-4

Edition 1.1 2000-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems

Appareils électromédicaux –
Partie 1-4: Règles générales de sécurité – Norme collatérale: Systèmes électromédicaux programmables

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX **CM**

ICS 11.040.01

ISBN 2-8318-5219-6

CONTENTS

Page

FOREWORD 3
INTRODUCTION 5

Clause

SECTION 1: GENERAL

1 Scope, object and relationship to other standards 6
1.201 Scope 6
1.202 Object 6
1.203 Relationship to other standards 7
2 Terminology and definitions 7
2.201 Defined terms 7
2.202 Degrees of requirements and miscellaneous terms 9
6 Identification, marking and documents 9
6.8 ACCOMPANYING DOCUMENTS 9

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

52 Abnormal operation and fault conditions 10
52.201 Documentation 10
52.202 RISK management plan 1 2
52.203 DEVELOPMENT LIFE-CYCLE 12
52.204 RISK management process 13
52.205 Qualification of personnel 15
52.206 Requirement specification 15
52.207 Architecture 15
52.208 Design and implementation 16
52.209 VERIFICATION 16
52.210 VALIDATION 16
52.211 Modification 17
52.212 Assessment 17

Annexes

AAA – Terminology – Index of defined terms 18
BBB – Rationale 19
CCC – RISK concepts 21
DDD – DEVELOPMENT LIFE-CYCLE 27
EEE – Examples for PEMS/PESS structures 31
FFF – Bibliography 33

Figures

201 – Content of RISK MANAGEMENT FILE and RISK MANAGEMENT SUMMARY 11
CCC.1 – RISK chart 22
CCC.2 – RISK management process 24
DDD.1 – A DEVELOPMENT LIFE-CYCLE model for PEMS 28
EEE.1 – Examples of PEMS/PESS structures 32

Table DDD.1 – Suggested correlation of the documentation requirement to the DEVELOPMENT LIFE-CYCLE phases 30

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems

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 60601-1-4 has been prepared by IEC technical committee 62: Electrical equipment in medical practice. It constitutes a Collateral Standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

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).

This consolidated version of Collateral Standard IEC 60601-1-4 consists of the first edition (1996) [documents 62/83/FDIS and 62/87/RVD] and its amendment 1 (1999) [documents 62/114/FDIS and 62/120/RVD].

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience.

It bears the edition number 1.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

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

Subclauses and figures which 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.

Annex AAA forms an integral part of this Collateral Standard.

Annexes BBB, CCC, DDD, EEE and FFF are for information only.

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

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, general statements, exceptions and references: smaller type;

– *test specifications and headings of subclauses: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF IEC 60601-1-1 OR OF THIS COLLATERAL STANDARD OR IN IEC 60788: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

INTRODUCTION

Computers are increasingly used in MEDICAL ELECTRICAL EQUIPMENT, often in critical-safety roles. The use of computing technologies in MEDICAL ELECTRICAL EQUIPMENT introduces a level of complexity which is exceeded only by the biological systems of the PATIENTS the MEDICAL ELECTRICAL EQUIPMENT is intended to diagnose and/or treat. This complexity means that systematic failures can escape practical accepted limits of testing. Accordingly, this safety standard goes beyond traditional testing and assessment of the finished MEDICAL ELECTRICAL EQUIPMENT and includes requirements for the processes by which the MEDICAL ELECTRICAL EQUIPMENT is developed. Testing of the finished product is not, by itself, adequate to address the SAFETY of complex MEDICAL ELECTRICAL EQUIPMENT.

This standard is a Collateral Standard to the General Standard. It requires that a process be followed and that a record of that process be produced to support the SAFETY of MEDICAL ELECTRICAL EQUIPMENT incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS. The concepts of RISK management and a DEVELOPMENT LIFE-CYCLE that are the basis of this standard can also be of value in the development of MEDICAL ELECTRICAL EQUIPMENT that does not include a PROGRAMMABLE ELECTRONIC SUBSYSTEM.

The effective application of the standard will require, subject to the task in hand, competency in the following:

- application of the specific MEDICAL ELECTRICAL EQUIPMENT with emphasis on SAFETY considerations;
- MEDICAL ELECTRICAL EQUIPMENT development process;
- methods by which SAFETY is assured;
- techniques of RISK analysis and RISK control.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems

SECTION 1: GENERAL

1 Scope, object and relationship to other standards

1.201 Scope

This Collateral Standard applies to the SAFETY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS), hereinafter referred to as PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).

NOTE Some systems which incorporate software and are used for medical purposes fall outside the scope of this Collateral Standard, e.g. many medical informatics systems. The distinguishing factor/criterion is whether or not the system satisfies the definition of MEDICAL ELECTRICAL EQUIPMENT in 2.2.15 of IEC 60601-1 or the definition of MEDICAL ELECTRICAL SYSTEM in 2.203 of IEC 60601-1-1.

1.202 Object

This Collateral Standard specifies requirements for the process by which a PEMS is designed. This Collateral Standard also serves as the basis of requirements of Particular Standards, including serving as a guide to SAFETY requirements for the purpose of reducing and managing RISK. This Collateral Standard is addressed to:

a) certification bodies;

b) MANUFACTURERS;

c) writers of Particular Standards.

This standard covers:

d) requirement specification;

e) architecture;

f) detailed design and implementation including software development;

g) modification;

h) VERIFICATION and VALIDATION;

j) marking and ACCOMPANYING DOCUMENTS.

Aspects not covered by this standard include:

k) hardware manufacturing;

l) software replication;

m) installation and commissioning;

n) operation and maintenance;

o) decommissioning.

1.203 Relationship to other standards

1.203.1 IEC 60601-1

For MEDICAL ELECTRICAL EQUIPMENT, this Collateral Standard complements IEC 60601-1 and its amendments.

When referring to IEC 60601-1 or to this Collateral Standard, either individually or in combination, the following conventions are used:

- "the General Standard" designates IEC 60601-1 alone;
- "this Collateral Standard" designates IEC 60601-1-4 alone;
- "this Standard" designates the combination of the General Standard and this Collateral Standard.

1.203.2 Particular Standards

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.203.3 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment No. 1 (1991)
Amendment No. 2 (1995)

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral Standard: Safety requirements for medical electrical systems*

IEC 60788:1984, *Medical radiology – Terminology*

ISO 9000-3:1991, *Quality management and quality assurance standards – Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

ISO 9001:1994, *Quality systems – Model for quality assurance in design, development, production, installation and servicing*

2 Terminology and definitions

2.201 Defined terms

In this Collateral Standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in the General Standard, IEC 60601-1-1, this Collateral Standard or IEC 60788.