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60601-1-2 : 1993
BS 5724 :
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1993

Medical electrical equipment

Part 1. General requirements for safety

Section 1.2 Collateral standard: Electromagnetic compatibility — Requirements and tests

The European Standard EN 60601-1-2 : 1993 has the status of a British Standard

Appareils électromédicaux
Première partie. Règles générales de sécurité
Section 1.2 Norme Collatérale: Compatibilité électromagnétique
Prescriptions et essais

Medizinische elektrische Geräte
Teil 1. Allgemeine Anforderungen an die Sicherheit
Abschnitt 1.2 Ergänzungs-Norm:
Elektromagnetische Verträglichkeit
Anforderungen und Prüfungen

UDC 615.841 : 621.37.001.365 : 620.1 : 614.8

BSI STANDARDS

Cooperating organizations

The European Committee for Electrotechnical Standardization (CENELEC), under whose supervision this European Standard was prepared, comprises the national committees of the following countries:

Austria	Italy
Belgium	Luxembourg
Denmark	Netherlands
Finland	Norway
France	Portugal
Germany	Spain
Greece	Sweden
Iceland	Switzerland
Ireland	United Kingdom

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 August 1993

The following BSI references relate to the work on this standard:
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Draft for comment 91/55220 DC

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Amendments issued since publication

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Contents

National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is the English language version of EN 60601-1-2 : 1993 *Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility — Requirements and tests*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-1-2 : 1993 published by the International Electrotechnical Commission (IEC).

This Collateral Standard amends BS 5724 : Part 1 : 1989 hereinafter called the General Standard. The requirements of this Collateral Standard are in addition to those of the General Standard. As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB etc.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-1-2

May 1993

UDC 615.841 : 621.37.001.365 : 620.1 : 614.8

Descriptors: Electromedical equipment, safety, electromagnetic compatibility

English version

Medical electrical equipment
Part 1: General requirements for safety
2. Collateral Standard: Electromagnetic compatibility — Requirements and tests

(IEC 601-1-2 : 1993)

Appareils électromédicaux
Première partie: Règles générales de sécurité
2. Norme Collatérale: Compatibilité électromagnétique —
Prescriptions et essais
(CEI 601-1-2 : 1993)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die Sicherheit
2. Ergänzungs-Norm: Elektromagnetische Verträglichkeit —
Anforderungen und Prüfungen
(IEC 601-1-2 : 1993)

This European Standard was approved by CENELEC on 1992-09-15. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

A draft European Standard concerning the electromagnetic compatibility of medical electrical equipment was submitted to the Unique Acceptance Procedure (UAP) as prEN 50097 in December 1991.

The 73rd Technical Board of CENELEC approved the draft on 1992-09-15, but decided that the standard would be issued as EN 60601-1-2 (endorsement of IEC 601-1-2, yet to be published).

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1993-11-30
- latest date of withdrawal of conflicting national standards (dow) 1995-12-31

For products which have complied with the relevant national standard before 1995-12-31, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-12-31.

EN 60601-1-2 constitutes a Collateral Standard to EN 60601-1 : Medical electrical equipment — Part 1: General requirements for safety, hereinafter referred to as the General Standard.

In the EN 60601 series 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).

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.

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 and headings of subclauses: in italic type;
- terms defined in clause 2 of the General Standard of this Collateral Standard: SMALL CAPITALS.

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.

Annexes designated 'normative' are part of the body of the standard. Annexes designated 'informative' are given only for information. In this standard, annex AAA is informative and annex ZAA is normative. Annex ZAA has been added by CENELEC.

An index reproduces in alphabetic order all the terms defined in clause 2, Terminology and definitions.

Editorial note. Annex BBB is replaced by annex ZAA.

CONTENTS

INTRODUCTION

The need for establishing specific ELECTROMAGNETIC COMPATIBILITY standards for medical electrical equipment and systems (both referred to as EQUIPMENT and/or SYSTEMS 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/or SYSTEMS;
- non-medical 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/or SYSTEMS.

This standard is based on existing IEC standards prepared by SC 62A, TC 65 (Industrial-process measurement and control), TC 77 (Electromagnetic compatibility between electrical equipment including networks) and CISPR (International special committee on radio interference).

The ELECTROMAGNETIC COMPATIBILITY requirements contained in this standard are generally applicable to EQUIPMENT and/or SYSTEMS as described in 1.201. For certain types of EQUIPMENT and/or SYSTEMS, these requirements have to be supplemented or modified by the special requirements of a Particular Standard. Where Particular Standards exist, this Collateral Standard should not be used alone. Special care is required in applying this Collateral Standard to EQUIPMENT and/or SYSTEMS for which no Particular Standard exists.

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

2. Collateral Standard: Electromagnetic compatibility – Requirements and tests

SECTION 1: GENERAL

1 Scope and object

1.201 *Scope*

This standard applies only to MEDICAL ELECTRICAL EQUIPMENT, MEDICAL ELECTRICAL SYSTEMS, INFORMATION TECHNOLOGY EQUIPMENT used in medical electrical application, and all other equipment forming part of MEDICAL ELECTRICAL SYSTEMS, hereinafter referred to as EQUIPMENT and/or SYSTEM(S).

1.202 *Object*

This standard specifies general requirements and tests for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and/or SYSTEMS and serves as the basis of possible additional ELECTROMAGNETIC COMPATIBILITY requirements and tests of Particular Standards.

2 Terminology and definitions

For the purposes of this standard, the following additional definitions apply:

2.201 *LIFE SUPPORTING EQUIPMENT and/or SYSTEM*

EQUIPMENT and/or SYSTEM which is intended to keep PATIENTS alive and/or to warn against the occurrence of a life-threatening situation and whose unannounced failure is likely to lead to serious injury or death of a PATIENT.

2.202 *PATIENT COUPLED EQUIPMENT and/or SYSTEM*

EQUIPMENT and/or SYSTEM containing at least one APPLIED PART whose physical contact with the PATIENT provides a sensing or treatment point necessary for the normal operation of the EQUIPMENT and/or SYSTEM and provides a path for conductively, capacitively, or inductively coupled electromagnetic energy. This does not include PATIENT supports.

2.203 *EMC Definitions from IEC 50(161)*

2.203.1 *ELECTROMAGNETIC ENVIRONMENT*

The totality of electromagnetic phenomena existing at a given location. [IEV 161-01-01]

2.203.2 *ELECTROMAGNETIC NOISE*

A time-varying electromagnetic phenomenon apparently not conveying information and which may be superimposed on or combined with a wanted signal. [IEV 161-01-02]

*2.203.3 *ELECTROMAGNETIC DISTURBANCE*

Any electromagnetic phenomenon which may degrade the performance of an EQUIPMENT and/or SYSTEM. [IEV 161-01-05, modified]

NOTE - An electromagnetic disturbance may be an ELECTROMAGNETIC NOISE, an unwanted signal or a change in the propagation medium itself.

2.203.4 *ELECTROMAGNETIC COMPATIBILITY: EMC* (abbreviation)

The ability of an EQUIPMENT and/or SYSTEM to function satisfactorily in its ELECTROMAGNETIC ENVIRONMENT without introducing intolerable ELECTROMAGNETIC DISTURBANCES to anything in that environment. [IEV 161-01-07]

2.203.5 *(ELECTROMAGNETIC) EMISSION*

The phenomenon by which electromagnetic energy emanates from a source. [IEV 161-01-08]

2.203.6 *DEGRADATION (of performance)*

An undesired departure in the operational performance of any EQUIPMENT and/or SYSTEM from its intended performance. [IEV 161-01-19, modified]

NOTE - The term "degradation" can apply to temporary or permanent failure.

2.203.7 *IMMUNITY (to a disturbance)*

The ability of an EQUIPMENT and/or SYSTEM to perform without DEGRADATION in the presence of an ELECTROMAGNETIC DISTURBANCE. [IEV 161-01-20, modified]

2.203.8 *(ELECTROMAGNETIC) SUSCEPTIBILITY*

The inability of an EQUIPMENT and/or SYSTEM to perform without DEGRADATION in the presence of an ELECTROMAGNETIC DISTURBANCE. [IEV 161-01-21, modified]

NOTE - SUSCEPTIBILITY is a lack of IMMUNITY.

2.203.9 *ELECTROSTATIC DISCHARGE: ESD* (abbreviation)

A transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact. [IEV 161-01-22]

2.203.10 *TRANSIENT (adjective and noun)*

Pertaining to or designating a phenomenon or a quantity which varies between two consecutive steady states during a time interval short compared with the time-scale of interest. [IEV 161-02-01]

2.203.11 *PULSE*

An abrupt variation of short duration of a physical quantity followed by a rapid return to the initial value. [IEV 161-02-02]

2.203.12 *BURST (of PULSES or oscillations)*

A sequence of a limited number of distinct PULSES or an oscillation of limited duration. [IEV 161-02-07]

2.203.13 *CLICK*

An ELECTROMAGNETIC DISTURBANCE which, when measured in a specified way, has a duration not exceeding a specified value. [IEV 161-02-15]

NOTE - See CISPR 14.

*2.203.14 *CLICK RATE*

The number of CLICKS exceeding a specified level, per unit of time, usually one minute. [IEV 161-02-16, modified]

2.203.15 *INFORMATION TECHNOLOGY EQUIPMENT: ITE* (abbreviation)

EQUIPMENT designed for the purpose of:

a) receiving data from an external source (such as a data input line or via a keyboard);

b) performing some processing functions on the received data (such as computation, data transformation or recording, filing, sorting, storage, transfer of data);

c) providing a data output (either to other equipment or by the reproduction of data or images).

NOTE - This definition includes electrical or electronic units or sytems which predominently generate a multiplicity of periodic binary pulsed electrical or electronic waveforms and are designed to perform data processing functions such as word processing, electronic computation, data transformation, recording, filing, sorting, storage, retrieval and transfer, and reprodution of data as images. [IEV 161-05-04]

2.203.16 *VOLTAGE CHANGE*

A variation of the r.m.s. or peak value of a voltage between two consecutive levels sustained for definite but unspecified durations. [IEV 161-08-01]

*2.203.17 *VOLTAGE FLUCTUATION*

A series of *VOLTAGE CHANGES* either random or cyclic. [IEV 161-08-05, modified]

2.203.18 *VOLTAGE DIP*

A sudden reduction of the voltage at a point in an electrical system followed by voltage recovery after a short period of time from a few cycles to a few seconds. [IEV 161-08-10]

2.203.19 *VOLTAGE SURGE*

A TRANSIENT voltage wave propagating along a line or a circuit and characterized by a rapid increase followed by a slower decrease of the voltage. [IEV 161-08-11]

2.204 *Definition from IEC 601-1-1: Safety requirements for medical electrical systems*

2.204.1 *MEDICAL ELECTRICAL SYSTEM* (hereinafter referred to as: *SYSTEM*)

Totality of more than one item of MEDICAL ELECTRICAL EQUIPMENT or of MEDICAL ELECTRICAL EQUIPMENT in combination with other non-medical electrical equipment that by coupling behaves as a unit with specified functions.

6 Identification, marking and documents

6.1.201 *Marking on the outside of EQUIPMENT or EQUIPMENT parts*

EQUIPMENT and/or SYSTEMS which intentionally apply RF energy for diagnosis or treatment shall be labelled with the following symbol for non-ionizing radiation (symbol 03-04 of IEC 878):

6.8.201 *ACCOMPANYING DOCUMENTS*

Wherever applicable, the following information shall be included in the ACCOMPANYING DOCUMENTS:

a) guidelines for avoiding or identifying and resolving adverse electromagnetic effects (see 36.201.1.3 and 36.202);

b) relevant restrictions in the use of the EQUIPMENT and/or SYSTEM (see 36.201.1.3 and 36.202);

c) justifications for CLICK allowances for other than radiology EQUIPMENT and/or SYSTEMS (see 36.201.1.4);

d) specification of IMMUNITY levels for PATIENT COUPLED EQUIPMENT and/or SYSTEMS (see 36.202.2.1);

e) justification for the application of lower IMMUNITY levels and actions which must be taken by the installer and/or USER as a consequence (see 36.202).

SECTIONS 2 to 4: Not used

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

36 Electromagnetic compatibility

36.201 *EMISSIONS*

36.201.1 *Radio frequency (RF) EMISSIONS*

*36.201.1.1 EQUIPMENT and/or SYSTEMS shall comply with the requirements of CISPR 11 with the alternatives noted below. Classification of EQUIPMENT and/or SYSTEMS is determined by the manufacturer based on intended use.

*36.201.1.2 *As an alternative to the assessment of conformity specified in clause 6 of CISPR 11, compliance of a specific model of* EQUIPMENT *and/or* SYSTEM *may be demonstrated by a type test of one unit on the premises of a typical* USER *or on a test site. As a second alternative, type testing of a sub-system of an* EQUIPMENT *and/or* SYSTEM *on a test site or in situ under normal conditions of operation may be used to demonstrate compliance.*

36.201.1.3 For EQUIPMENT and/or SYSTEMS which intentionally apply RF energy for diagnosis or treatment, the ACCOMPANYING DOCUMENTS shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects. If the use of the EQUIPMENT and/or SYSTEM is restricted due to its electromagnetic characteristics, relevant restrictions shall be described in the ACCOMPANYING DOCUMENTS. Such EQUIPMENT shall be labeled with the non-ionizing radiation symbol (symbol 03-04 of IEC 878).

*36.201.1.4 Limits shall be increased by 20 dB for medical radiology EQUIPMENT and/or SYSTEMS that are used in an intermittent mode according to the CLICK provisions of 4.2 of CISPR 14.

Appropriate allowances are permitted for other EQUIPMENT and/or SYSTEMS that use intermittent modes, according to the CLICK provisions of 4.2 of CISPR 14. Justification for such allowances shall be stated in the ACCOMPANYING DOCUMENTS.

*36.201.1.5 For EQUIPMENT and/or SYSTEMS which are PERMANENTLY INSTALLED in X-ray shielded locations, an increase in the field strength limits of 12 dB for tests performed on a test site is allowed.

Appropriate allowances are permitted for PERMANENTLY INSTALLED EQUIPMENT and/or SYSTEMS used in other shielded locations. Justification for the allowance shall be stated in the ACCOMPANYING DOCUMENTS.

*36.201.1.6 High frequency surgical EQUIPMENT

*36.201.1.7 Until test procedures are developed for PATIENT COUPLED EQUIPMENT and/or SYSTEMS, the manufacturer shall state in the ACCOMPANYING DOCUMENTS the test procedure used.

36.201.1.8 Class A EQUIPMENT and/or SYSTEMS (CISPR 11 classification) are allowed in domestic establishments when used under the jurisdiction of a health care professional.

NOTE - National authorities apply whatever measures they consider necessary to protect radio comunications.

36.201.2 *Low frequency EMISSIONS*

*36.201.2.1 *VOLTAGE FLUCTUATIONS and harmonic distortion*

No requirements for EQUIPMENT and/or SYSTEMS.

*36.201.2.2 *Magnetic field EMISSIONS*

36.202 *IMMUNITY*

This subclause specifies general IMMUNITY requirements.

If lower levels are justified, ACCOMPANYING DOCUMENTS shall contain the level, its justification, and any action which shall, as a consequence, be taken by the installer or USER.

ACCOMPANYING DOCUMENTS shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects. If the use of the EQUIPMENT and/or SYSTEM is restricted due to its electromagnetic characteristics, relevant restrictions shall be described in the ACCOMPANYING DOCUMENTS.

Compliance with the requirements given in 36.202.1 to 36.202.6 shall be checked by verifying that, under the specified conditions the EQUIPMENT and/or SYSTEM continues to perform its intended function as specified by the manufacturer or fails without creating a SAFETY HAZARD.

Type testing of sub-systems of PERMANENTLY INSTALLED EQUIPMENT and/or SYSTEMS is allowed for demonstrating compliance with the requirements given in 36.202.1 to 36.202.6 when these tests are performed using simulated normal operating conditions.

*36.202.1 *ELECTROSTATIC DISCHARGE*

EQUIPMENT and/or SYSTEMS shall comply with IEC 801-2. A level of 3 kV shall apply for contact discharge to conductive ACCESSIBLE PARTS and coupling planes. A level of 8 kV shall apply for air discharge to non-conductive ACCESSIBLE PARTS.

36.202.2 *Radiated radio-frequency electromagnetic fields*

*36.202.2.1 *Requirements*

a) EQUIPMENT and/or SYSTEMS shall comply with the future IEC 801-3 (second edition under consideration). A level of 3 V/m for the frequency range of 26 MHz – 1 GHz shall apply.

b) For EQUIPMENT and/or SYSTEMS specified for use only in X-ray shielded locations, the level shall be 1 V/m when tested on a test site without such shielding.

c) For EQUIPMENT and/or SYSTEMS specified for use only in other kinds of shielded locations, the level of 3 V/m may be decreased in proportion to the shielding effectiveness.

d) Manufacturers of PATIENT COUPLED EQUIPMENT and/or SYSTEMS shall specify IMMUNITY levels for their EQUIPMENT and/or SYSTEMS.

e) The manufacturer shall document the test methods used to verify compliance.

*36.202.2.2 *Test conditions*

a) *Amplitude modulation at a single modulation frequency within each funtionally significant signal processing passband of the EQUIPMENT and/or SYSTEM shall be used. For EQUIPMENT and/or SYSTEMS not having a defined passband, modulation shall be at 1 kHz.*

b) *For LIFE SUPPORTING EQUIPMENT and/or SYSTEMS, the test frequency shall be swept from 26 MHz to 1 GHz.*

c) *For other than LIFE SUPPORTING EQUIPMENT and/or SYSTEMS, the test shall be performed at all frequencies within the range 26 MHz to 1 GHz designated by the ITU[1] for ISM[2] use.*

d) *PATIENT COUPLED EQUIPMENT and/or SYSTEMS (see annex AAA).*

e) *Verification of compliance of PERMANENTLY INSTALLED EQUIPMENT and/or SYSTEMS other than LIFE SUPPORTING EQUIPMENT and/or SYSTEMS may be by type test at one installation site using the ambient sources occurring in that medical environment. In addition, testing shall be performed at frequencies in the range from 26 MHz to 1 GHz designated by the ITU for ISM use.*

36.202.3 *TRANSIENTS*

36.202.3.1 *BURSTS*

a) Test methods and instruments specified in IEC 801-4 shall apply. Plug connected EQUIPMENT and/or SYSTEMS shall meet a 1 kV IMMUNITY level at the MAINS PLUG. For PERMANENTLY INSTALLED EQUIPMENT and/or SYSTEMS the level of IMMUNITY at power supply input lines shall be 2 kV.

b) EQUIPMENT and/or SYSTEMS shall withstand 0,5 kV BURSTS for interconnecting lines longer than 3 m.

36.202.3.2 *SURGES*

Test methods and instruments which will be specified in the future IEC 801-5 (under consideration) shall apply. EQUIPMENT and/or SYSTEMS shall meet an IMMUNITY level at the mains of 1 kV in differential mode and 2 kV in common mode.

NOTES

1 Signal lines are not tested.

2 Telecommunication lines are covered by other standards.

3 Ring wave and damped oscillation tests are not applicable to EQUIPMENT and/or SYSTEMS.

*36.202.4 VOLTAGE DIPS, short interruptions and voltage variations on power supply input lines

*36.202.5 Conducted disturbances, induced by radio-frequency fields above 9 kHz

*36.202.6 Magnetic fields

SECTIONS 6 to 10: Not used

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1) International Telecommunication Union.

2) Industrial, Scientific and Medical.

Annex AAA
(informative)

General guidance and rationale

Subclause 2.203.3

In this Collateral Standard dealing with MEDICAL ELECTRICAL EQUIPMENT and/or SYSTEMS it has not been deemed adequate to suggest that an ELECTROMAGNETIC DISTURBANCE might "adversely affect living (or inert) matter". As a consequence, in an otherwise unchanged text, the corresponding phrase of IEV definition 161-01-05 has not been retained.

Subclause 2.203.14

IEV definition 161-02-16 has been editorially reworded to ensure that the "specified level exceeded" applies to the magnitude of the CLICKS and not to their number.

Subclause 2.203.17

No definition is available for the expression "voltage envelope", used in the original IEV 161-08-05 definition. As a consequence, and without altering its meaning, the text has been simplified.

Subclause 36.201.1.1

For MEDICAL ELECTRICAL EQUIPMENT and/or SYSTEMS the CISPR product family standard is used as a basic standard. In addition the CLICK provisions contained in CISPR 14 are used. See also definition in 2.204.1 (MEDICAL ELECTRICAL SYSTEM).

Subclause 36.201.1.2

EQUIPMENT and/or SYSTEMS are usually not mass produced; therefore, the statistical assessment of conformity specified in CISPR 11 is not required. For practical and economic reasons, testing of large EQUIPMENT and/or SYSTEMS in situ is allowed. Likewise, because of the variety of EQUIPMENT and/or SYSTEM configurations, testing of sub-systems is allowed.

Subclause 36.201.1.4

Because of the requirement to minimize image blurring and PATIENT dose, diagnostic radiology EQUIPMENT is designed to be operated at short exposure times. Statistical analysis indicated that 90 % to 95 % of all radiographs are taken using exposure times of less than 0,2 s. In addition the DUTY CYCLE is typically less than 0,5 % because of the load characteristics of the X-ray tube. Based on a statistical analysis, the estimated average CLICK RATE "N" is 3 and an allowance of:

20 x log (30/3) dB = 20 dB is appropriate.

Subclause 36.201.1.5

PERMANENTLY INSTALLED EQUIPMENT and/or SYSTEMS used in radiology are always situated in X-ray shielded locations. Testing indicates that such enclosures provide 14 dB or more of RF attenuation above 26 MHz. This shielding is equally effective for other EQUIPMENT and/or SYSTEMS intended only for use in such locations; therefore, a 12 dB allowance is applicable to all such EQUIPMENT and/or SYSTEMS when measured on a test site.

Subclause 36.201.1.6

Specifications of limits and test methodology for high fequency surgical EQUIPMENT are under consideration[1)].

Subclause 36.201.1.7

Specifications for test procedures for PATIENT COUPLED EQUIPMENT and/or SYSTEMS are under consideration[2)].

Subclause 36.201.2.1

EQUIPMENT and/or SYSTEMS are an insignificant load factor on the power network and do not create daily peak power demands as do consumer products (e.g. TV sets). Moreover, most EQUIPMENT and/or SYSTEMS are not connected to the public low voltage supply system.

Subclause 36.201.2.2

Limits for magnetic field EMISSIONS below 9 kHz are under consideration[3)].

Subclause 36.202.1

Levels were chosen to harmonize requirements with the recommendation in the future CISPR 24, due to the presence of ITE in MEDICAL ELECTRICAL EQUIPMENT and/or SYSTEMS.

Subclause 36.202.2.1 a)

At the time of publication of this standard the second edition of IEC 801-3 was not approved. This posed a difficulty since the frequency range of 26 MHz to 1 GHz, although restated in this standard, came from a draft revision of IEC 801-3, 1st edition, 1984. The use of amplitude modulation found in this standard also came from the draft revision of IEC 801-3 which, although not restated in this standard, called for 80 % amplitude modulation to be used. As a result, the use of "future" edition was used in this standard when addressing IEC 801-3, since the first edition used a different frequency range and no amplitude modulation.

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1) Under consideration by CISPR/B.

2) Under consideration by WG 13 of SC 62A.

3) Under consideration by TC 77 and WG 13 of SC 62A.

Subclause 36.202.2.1 b)

For EQUIPMENT and/or SYSTEMS specified for use only in X-ray shielded rooms, the shielding provides a radio-frequency attenuation of 14 dB or more in the frequency range above 26 MHz.

Subclause 36.202.2.1 d)

Applicable IMMUNITY levels are under consideration[2]. The 3 V/m IMMUNITY level may be inappropriate because the physiological signals measured can be substantially below those induced by a field strength of 3 V/m.

Subclause 36.202.2.2 d)

Inclusion of the PATIENT may significantly affect the ELECTROMAGNETIC ENVIRONMENT of the EQUIPMENT and/or SYSTEM under test (the PATIENT may function as an antenna). For this reason, the development of adequate PATIENT models and test methodology will require extensive research for each type of PATIENT coupling. Applicable IMMUNITY test methodologies for PATIENT COUPLED EQUIPMENT and/or SYSTEMS are under consideration[2].

Subclause 36.202.2.2 e)

Installation and removal of PERMANENTLY INSTALLED EQUIPMENT and/or SYSTEM on a test site can represent heavy investments in testing resources. Many such EQUIPMENT and/or SYSTEMS have a large number of different configurations, making it impractical to test each one. For these reasons sub-system testing under simulated normal operating conditions (example: cabling) and installation type testing are the only practical alternatives. EQUIPMENT and/or SYSTEMS which comply under such conditions are unlikely to demonstrate RF IMMUNITY problems.

Subclause 36.202.4

Applicable IMMUNITY levels and test methodology for VOLTAGE DIPS, short interruptions and voltage variations on power supply input lines, are under consideration[3].

Subclause 36.202.5

Limits and test methodology for conducted disturbances, induced by radio-frequency fields above 9 kHz, are under consideration[2] [4].

Subclause 36.202.6

Limits and test methodology for magnetic fields are under consideration[5].

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2) See note page 27.

3) See note page 27.

4) Under consideration by SC 65A and SC 77B.

5) Under consideration by TC 77.

INDEX OF DEFINED TERMS

Annex ZAA (normative)

Other international publications quoted in this standard with the references of the relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC publication	Date	Title	EN/HD	Date
50(161)	1990	*International Electrotechnical Vocabulary (IEV) — Chapter 161: Electromagnetic compatibility*	—	—
601-1	1988	*Medical electrical equipment*	EN 60601-1	1990
A1	1991	Part 1 : *General requirements for safety*	A1	1993
			A11, A12	1993
601-1-1	1992	Part 1. *General requirements for safety* — 1. *Collateral standard: Safety requirements for medical electrical systems*	—	—
801-1	1984	*Electromagnetic compatibility for industrial-process measurement and control equipment* — Part 1: *General introduction*	HD 481.1 S1	1987
801-2	1991	Part 2: *Electrostatic discharge requirements*	EN 60801-2	1993
801-3	—*	Part 3: *Immunity to radiated radio-frequency electromagnetic fields* (second edition under consideration)	—	—
801-4	1988	Part 4: *Electrical fast transient/burst requirements*	—	—
801-5	—	Part 5: *Voltage surge immunity requirements* (under consideration)	—	—
878	1988	*Graphical symbols for electrical equipment in medical practice*	—	—
CISPR 11 (mod)	1990	*Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment*	EN 55011†	1991
CISPR 14 (mod)	1985	*Limits and methods of measurement of radio interference characteristics of household electrical appliances, portable tools and similar electrical apparatus*	EN 55014‡	1987

* IEC 801-3 : 1984 was harmonized as HD 481.3 S1 : 1987
† The title of EN 55011 : 1991 is: Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment
‡ EN 55014 is superseded by EN 55014 : 1993 which is based on CISPR 14 : 1993

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National annex NA (informative)

Committees responsible

The United Kingdom participation in the preparation of this European Standard was entrusted by the Heath Care Standards Policy Committee (HCC/-) to Technical Committee HCC/64, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health Care Industries
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Ministry of Defence
Royal College of Radiologists
Scottish Health Services
Sira Limited

National annex NB (informative)

Cross-references

Publication referred to	Corresponding British Standard
IEC 50(161) : 1990	BS 4727 *Glossary of electrotechnical, power, telecommunications, electronics, lighting and colour terms*
	Group 09 : 1991 *Electromagnetic compatibility*
IEC 601-1-1 : 1992	BS 5724 *Medical electrical equipment*
	Section 1.1 : 1992 *Collateral standard. Safety requirements for medical electrical systems*
IEC 801-1 : 1984	BS 6667 *Electromagnetic compatibility for industrial-process measurement and control equipment*
	Part 1 : 1985 *General introduction*
IEC 801-2 : 1991	BS EN 60801 *Electromagnetic compatibility for industrial-process measurement and control equipment*
	Part 2 : 1993 *Electrostatic discharge requirements*
IEC 801-3 : 1984	BS 6667 *Electromagnetic compatibility for industrial-process measurement and control equipment*
	Part 3 : 1985 *Method of evaluating susceptibility to radiated electromagnetic energy*
IEC 878 : 1988	BS 7139 : 1989 *Guide to graphical symbols for use on medical electrical equipment*

BS EN 60601-1-2 : 1993
BS 5724 : Section 1.2 : 1993
IEC 601-1-2 : 1993

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