

Medical electrical equipment —

Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV

The European Standard EN 60601-2-1:1998, with the incorporation of amendment A1:2002, has the status of a British Standard

ICS 11.040.50; 13.280

National foreword

This British Standard is the English language version of EN 60601-2-1:1998, including amendment A1:2001. It is identical with IEC 60601-2-1:1998, including amendment 1:2002. It supersedes BS 5724-2-1:1989 and BS 5724-2-1-1:Supplement No. 1:1991 which are withdrawn. As in the General Standard (BS 5724-1:1989), 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 101. Additional annexes are lettered AA, BB, etc. and additional items aa), bb), etc. The changes from the text of the General Standard are specified by the use of the following words.

- “Replacement” means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.
- “Amendment” means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by the text of this standard.
- “Addition” means that the text of this standard is additional to the requirements of the General Standard.

The UK participation in its preparation was entrusted to Technical Committee CH/81, Radiotherapy equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary. From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Additional information. The following print types are used in this standard.
Requirements, with which compliance can be tested, and definitions: in roman type.
Explanations, advice, general statements, exceptions and references: in small roman type.
Test procedures: in *italic* type.
Terms defined in BS 5724-1 or in BS 6641: SMALL CAPITALS.
For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.
This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.
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Medical electrical equipment — Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV

(includes amendment A1:2002)

(IEC 60601-2-1:1998 + A1:2002)

Appareils électromédicaux —

Partie 2-1: Règles particulières de sécurité pour
les accélérateurs d'électrons dans la gamme de
1 MeV à 50 MeV —

(inclut l'amendement A1:2002)

(CEI 60601-2-1:1998 + A1:2002)

Medizinische elektrische Geräte —

Teil 2-1: Besondere Festlegungen für die
Sicherheit von Elektronenbeschleuniger im
Bereich von 1 MeV bis 50 MeV

(enthält Änderung A1:2002)

(IEC 60601-2-1:1998 + A1:2002)

This European Standard was approved by CENELEC on 1998-08-01; amendment A1 was approved by CENELEC on 2002-06-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
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Foreword

The text of document 62C/232/FDIS, future edition 2 of IEC 60601-2-1, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-1 on 1998-08-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1999-05-01
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Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex AA and Annex BB are informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-1:1998 was approved by CENELEC as a European Standard without any modification.

In the official version, for Annex BB, Bibliography, the following notes have to be added for the standards indicated:

- IEC 60601-1-1
- NOTE Harmonized as EN 60601-1-1:1993 (not modified).
- IEC 60601-1-3
- NOTE Harmonized as EN 60601-1-3:1994 (not modified).

Foreword to amendment A1

The text of document 62C/329/FDIS, future amendment 1 to IEC 60601-2-1:1998, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-1:1998 on 2002-06-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2003-03-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2005-06-01

Endorsement notice

The text of amendment 1:2002, to the International Standard IEC 60601-2-1:1998, was approved by CENELEC as an amendment to the European Standard without any modification.

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Introduction

The use of ELECTRON ACCELERATORS for RADIOTHERAPY purposes may expose PATIENTS to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the RADIATION adequately and/or if there are inadequacies in the design of the TREATMENT ROOM.

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of ELECTRON ACCELERATORS for use in RADIOTHERAPY; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such EQUIPMENT; it places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists and where an INTERLOCK then operates to prevent continued operation of the EQUIPMENT.

Clause **29** contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition. TYPE TESTS that are performed by the MANUFACTURER, and/or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are SPECIFIED for each requirement.

It should be understood that, before installation, a MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS. Data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the EQUIPMENT at installation.

Subclause **29.3.1.1** of IEC 60601-2-1:1998 sets limits to X-ray leakage radiation through beam limiting devices (BLDs) in the patient plane in order to reduce the detrimental effects on the patient due to leakage radiation. This clause restricts leakage through the main X and Y BLDs to a maximum of 2 % and an average of 0,5 %. Multi-element BLDs were assumed to replace a beam shielding block which attenuated the beam to about 5 %, and this was the upper limit applied to multi-element BLDs.

With the growth of techniques such as conformal therapy and IMRT, multi-element BLDs (which allow higher leakage levels) are being used to shield more of the radiation field area than was the case with conventional techniques using beam blocks. It is now proposed in the replacement subclause **29.3.1.1** to set a leakage tolerance on the total beam limiting system (the X and Y BLDs themselves may be single element, multi-element, or a combination of both) and to limit the leakage to an average of 0,75 %.

Section 1. General

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

1.1 Scope

Addition:

This Particular Standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation¹⁾ aspects of ELECTRON ACCELERATORS²⁾:

- intended for RADIOTHERAPY in human medical practice, including those in which the selection and DISPLAY of operating parameters can be controlled automatically by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS);
- that, under NORMAL CONDITIONS (NC) and in NORMAL USE, deliver a RADIATION BEAM of X-RADIATION and/or ELECTRON RADIATION having:
 - NOMINAL ENERGY in the range 1 MeV to 50 MeV;
 - maximum ABSORBED DOSE³⁾ rates between $0,001 \text{ Gy} \times \text{s}^{-1}$ and $1 \text{ Gy} \times \text{s}^{-1}$ at 1 m from the RADIATION SOURCE;
 - NORMAL TREATMENT DISTANCES (NTDs) between 0,5 m and 2 m from the RADIATION SOURCE;

and:

- intended to be:
 - for NORMAL USE, operated under the authority of appropriately licensed or QUALIFIED PERSONS by OPERATORS having the required skills for a particular medical application, for particular specified clinical purposes, e.g. STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY;
 - maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE;
 - subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON;
 - used within the environmental and electrical supply conditions SPECIFIED in the technical description.

1.2 Object

Addition:

This Particular Standard establishes requirements to ensure the IONIZING RADIATION safety and enhanced electrical and mechanical safety of ELECTRON ACCELERATORS, and specifies tests to check compliance with those requirements.

NOTE The adoption of this standard helps to ensure that the EQUIPMENT:

- maintains PATIENT safety during EQUIPMENT movements and failure of the SUPPLY MAINS;
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE;
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, by utilizing STATIONARY RADIOTHERAPY, MOVING BEAM RADIOTHERAPY, RADIATION BEAM modifying devices, etc., without causing unnecessary risk to the PATIENT, the OPERATOR, other persons or the environment.

¹⁾ In this Particular Standard, all references to installation refer to installation in the USER'S premises.

²⁾ See ICRP 33 (128) – (134) and (144) – (156).

³⁾ In this Particular Standard, all reference to ABSORBED DOSE refer to ABSORBED DOSE in water.

1.3 Particular Standards

Additional subclauses:

1.3.101 Relationship to other standards and documents

NOTE See Appendix L for normative references.

1.3.102 IEC 60601-1

The requirements of this Particular Standard take priority over those of all other standards; it is to be read in conjunction with IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety* with its amendments 1 (1991) and 2 (1995) — hereinafter referred to as the General Standard — which it amends and supplements. As in the General Standard, the requirements are followed by compliance tests.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification. Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard. Unless otherwise stated, all clauses of the General Standard shall apply. The term “this Standard” is used throughout to refer to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General and Collateral Standards are SPECIFIED by the use of the following words.

- “Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.
- “Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.
- “Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables that are additional to those of the General Standard are numbered starting from 101: additional annexes are lettered AA, BB, etc., and additional items *aa*), *bb*), etc.

1.3.103 IEC 61217

This standard gives guidance on the designation of EQUIPMENT movements, the marking of scales, their zero positions and the direction of movement with increasing value (see **6.3.101**).

1.5 Collateral Standards

Additional subclauses:

1.5.101 IEC 60601-1-1

This Collateral Standard does not apply.

1.5.102 IEC 60601-1-2

ELECTROMAGNETIC COMPATIBILITY — Requirements and tests; see Clause **36**.

NOTE IEC 60601-1-2 applies to MEDICAL ELECTRICAL EQUIPMENT and ITE (INFORMATION TECHNOLOGY EQUIPMENT) used in medical applications. ELECTRON ACCELERATORS and their integral ITE are not excluded from compliance with IEC 60601-1-2; it has not been possible at this date to determine fully whether further amendments to its requirements or tests will need to be made in addition to those given in Clause **36** of this Particular Standard.

1.5.103 IEC 60601-1-3

This Collateral Standard does not apply.

1.5.104 IEC 60601-1-4

PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS) — Requirements and tests: see **29.1.15** and **52.1b**).

2 Terminology and definitions

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

Addition:

NOTE Annex AA lists defined terms alphabetically with their source reference.

Additional definitions:

2.1.101

CONTROLLING TIMER

device to measure the time during which IRRADIATION occurs and, if a predetermined time is reached, TO TERMINATE IRRADIATION

2.1.102

ELECTRON BEAM APPLICATOR

BEAM LIMITING DEVICE for ELECTRON RADIATION BEAMS

2.1.103

GANTRY

that part of the EQUIPMENT supporting the RADIATION HEAD

2.1.104

GEOMETRICAL RADIATION FIELD

geometrical projection of the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the REFERENCE AXIS, as seen from the centre of the front surface of the TARGET/ELECTRON RADIATION window. The GEOMETRICAL RADIATION FIELD may be defined at any distance from the front surface of the TARGET for X-RADIATION, or from the ELECTRON RADIATION window for ELECTRON RADIATION

2.1.105

HARD-WIRED

term used where the features of a system can be modified only by physically removing and re-routing wires

2.1.106

INTERRUPTION OF IRRADIATION/TO INTERRUPT IRRADIATION

stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

2.1.107

MOVING BEAM RADIOTHERAPY

RADIOTHERAPY with any planned displacement of the RADIATION FIELD or PATIENT relative to each other or with any planned change of ABSORBED DOSE distribution

2.1.108

NOMINAL ENERGY (hereinafter referred to as ENERGY)

- a) for ELECTRON RADIATION, ENERGY stated by the MANUFACTURER to characterize the RADIATION BEAM. This ENERGY is approximately equal to the most probable energy at the surface of the measuring PHANTOM, $E_{p,0}$ (See ICRU Report 35: Section 3.3; Energy, $E_{p,0}$)
- b) for X-RADIATION, the ENERGY stated by the MANUFACTURER to characterize the RADIATION BEAM

2.1.109

NORMAL TREATMENT DISTANCE (abbreviation: NTD)

- a) for ELECTRON IRRADIATION, SPECIFIED distance measured along the REFERENCE AXIS from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane
- b) for X-IRRADIATION, SPECIFIED distance measured along the REFERENCE AXIS from the front surface of the TARGET to the ISOCENTRE or, for EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

2.1.110

PASSWORD

for EQUIPMENT under the control of a PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS), sequence of keystrokes that permits OPERATOR access for NORMAL USE or to reset INTERLOCKS and, with a different sequence of keystrokes, permits access for adjustment and maintenance

2.1.111

PATIENT SUPPORT

the assembly of EQUIPMENT that supports the PATIENT

2.1.112

PRIMARY/SECONDARY DOSE MONITORING COMBINATION

utilization of two DOSE MONITORING SYSTEMS where one is arranged to be the PRIMARY and the other the SECONDARY DOSE MONITORING SYSTEM

2.1.113

QUALIFIED PERSON

person recognised by a competent authority as having the requisite knowledge and training to perform particular duties

2.1.114

RADIATION TYPE

nature of the waves or corpuscles comprising the RADIATION, e.g. whether the RADIATION is X-RADIATION or ELECTRON RADIATION

2.1.115

REDUNDANT DOSE MONITORING COMBINATION

utilization of two DOSE MONITORING SYSTEMS where both systems are arranged to TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS

2.1.116

RELATIVE SURFACE DOSE

ratio of the ABSORBED DOSE on the REFERENCE AXIS, at the depth of 0,5 mm, to the maximum ABSORBED DOSE on the REFERENCE AXIS, both measured in a PHANTOM with its surface at a SPECIFIED distance

2.1.117

SITE TEST

after installation, test of an individual device or EQUIPMENT to establish compliance with SPECIFIED criteria

2.1.118

TERMINATION OF IRRADIATION/TO TERMINATE IRRADIATION

stopping of/to stop IRRADIATION and movements, with no possibility of restarting without the reselection of all operating conditions (i.e. returning/to return to the PREPARATORY STATE)

NOTE Events that TERMINATE IRRADIATION and stop movements include the following events:

- when the pre-selected value of DOSE MONITOR UNITS is reached;
- when the pre-selected value of elapsed time is reached;
- a deliberate manual act;
- the operation of an INTERLOCK;
- in MOVING BEAM RADIOTHERAPY, when the pre-selected value of an angular or linear dimension is exceeded.

2.1.119

TRANSMISSION DETECTOR

RADIATION DETECTOR through which the RADIATION BEAM passes

2.1.120

TYPE TEST

for a particular design of device or EQUIPMENT, test by the MANUFACTURER to establish compliance with SPECIFIED criteria

4 General requirements for tests

4.1 Tests

Additional subclause:

4.1.101 Test grades

Three grades of TYPE TEST and two of SITE TEST procedures are SPECIFIED in Clause 29 of this Particular Standard. Their requirements are as follows.

- *TYPE TEST grade A: An analysis of EQUIPMENT design, as related to the SPECIFIED RADIATION safety provisions, which shall result in a statement included in the technical description, regarding the working principles or constructional means by which the requirement is fulfilled.*
- *TYPE TEST/SITE TEST grade B: Visual inspection or functional test or measurement of the EQUIPMENT. The test shall be in accordance with the procedure SPECIFIED in this Particular Standard and shall be based on operating states, including fault condition states, which are achievable only without interference with the circuitry or construction of the EQUIPMENT.*
- *TYPE TEST/SITE TEST grade C: Functional test or measurement of the EQUIPMENT. The test shall be in accordance with the principle SPECIFIED in this Particular Standard. The SITE TEST procedure shall be included in the technical description. When the procedure involves operating states that require interference with circuitry or the construction of the EQUIPMENT, the test should be performed by, or under the direct supervision of, the MANUFACTURER or his agent.*

5 Classification

5.1 According to the type of protection against electric shock:

- CLASS I EQUIPMENT.

Replacement:

EQUIPMENT and its APPLIED PARTS shall be classified by marking and/or identification as described in Clause 6. This includes:

5.2 According to the degree of protection against electric shock:

- TYPE B APPLIED PARTS.

5.3 According to the degree of protection against ingress of water detailed in IEC 60529 [see 6.11)]

- IPX0, unless otherwise SPECIFIED.

5.4 According to the method(s) of sterilization or disinfection recommended in the INSTRUCTIONS FOR USE.

5.5 According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, or WITH OXYGEN OR NITROUS OXIDE:

- EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

5.6 According to the mode of operation:

- CONTINUOUS OPERATION WITH INTERMITTENT LOADING, unless otherwise SPECIFIED.

Addition:

Table 101 — Data required in the technical description to support Clause 29 SITE TEST compliance

Compliance subclause	Statement regarding data from TYPE TESTS grade A	Details of, and results from, TYPE TESTS grade B	Details of, and results from, TYPE TESTS grade-C	SPECIFIC procedures and test conditions for SITE TESTS grade C
29.1.1.1	b) d) e)		d)	a) b) c)
29.1.1.2	a) b)		b) c)	b)
29.1.1.3	d) e) f)			
29.1.1.4	a) b) c)			b) c)
29.1.1.5	a)			b)
29.1.2	a) b) c)			b) c)
29.1.3	b) c) d) e)			b) c) d) e)
29.1.4	a) b) c) d) e) f) g)			
29.1.5	e)		e)	
29.1.6	e) h)		f) g)	e) f) g) h)
29.1.7.1				d)
29.1.7.2				d)
29.1.7.3.1	†			†
29.1.7.3.2				d)
29.1.9	b)			
29.1.10	e)			
29.1.11	†			
29.1.12	a) c)			
29.1.13	a)			
29.1.14	a) b)			a) b)
29.1.15	†			†
29.2.1	†			
29.2.2		†		
29.2.3			†	
29.3.1.1		a) b) c) d)		
29.3.1.2	c)	a)1), a)2), b)		c)
29.3.2		†		†
29.3.3		†		
29.3.4	†		† ← or →	†
29.4.1		a) b)		
29.4.2			†	
29.4.3	b)	a)		
29.4.4	†			
29.4.5		†		

NOTE † denotes requirement of subclause having no other specific identification.

6 Identification, marking and documents

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

d) *Minimum requirements for marking on EQUIPMENT and on interchangeable parts*

Addition:

The dimensions of the GEOMETRICAL RADIATION FIELD at NTD and the distance from the distal end to NTD shall be clearly legible on the outside of all interchangeable and non-adjustable BLDs and ELECTRON BEAM APPLICATORS.

Each manually interchangeable WEDGE FILTER shall be clearly marked to establish its identity.

z) *Removable protective means*

Addition:

Where the requirements of this item are wholly or partly met by the nature of the installation, compliance at installation should be checked by inspection; the results should be included in the SITE TEST report.

6.2 Marking on the inside of EQUIPMENT or EQUIPMENT parts

Addition:

aa) Removal of the covers of the RADIATION HEAD shall expose symbol 14 of Table D.1 of the General Standard, indicating "Attention, consult ACCOMPANYING DOCUMENTS".

6.3 Marking of controls and instruments

Additional subclause:

6.3.101 Provision of scales and indications for moving parts

The following shall be provided:

- a) a mechanical scale or a numerical indication for each available movement;
- b) a LIGHT FIELD, with an indication of the position of the REFERENCE AXIS;
- c) a scale or numerical indication of the distance along the REFERENCE AXIS from the front surface of the RADIATION SOURCE to the surface of the PATIENT (RADIATION SOURCE TO SKIN DISTANCE).

The designation, direction of increasing value and zero position of all movements shall comply with IEC 61217 (see Figure 108).

Compliance is checked by inspection.

6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition:

Where indicator lights are used on the TREATMENT CONTROL PANEL (TCP) or other control panels, the colours of the lights shall accord with the following:

- RADIATION BEAM "on" yellow⁴⁾
- READY STATE..... green⁴⁾
- urgent action required in response to an unintended state of operation..... red
- PREPARATORY STATE..... other colour

⁴⁾ In the TREATMENT ROOM or at other locations, these states may require urgent action or caution; different colours, in accordance with Table 3 of the General Standard, may therefore be used in such locations.

Light emitting diodes (LEDs) are not considered to be indicator lights when:

- on any one TCP, all indications for which no particular colour is required are given by LEDs of the same colour; and
- the indications for which particular colours are required are clearly distinguishable.

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Addition:

NOTE The INSTRUCTIONS FOR USE and technical description form part of the ACCOMPANYING DOCUMENTS. With the exception of data required in the technical description to support Clause 29 SITE TEST compliance, which are set out in Table 101, clauses and subclauses in this Particular Standard that require the provision of information in the ACCOMPANYING DOCUMENTS, INSTRUCTIONS FOR USE and technical description are given in Table 102.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

- INSTRUCTIONS FOR USE shall contain:
 - an explanation of the function of all INTERLOCKS and other RADIATION safety devices;
 - instructions for checking their correct operation;
 - a recommendation of the frequency with which such checks should be made;
 - the recommended inspection or replacement intervals for any parts having a safety function that are subject to impairment caused, during the NORMAL USE of the EQUIPMENT, by the effects of IONIZING RADIATION on the dielectric and/or mechanical strength of those parts.

j) Environmental protection

Addition:

NOTE The USER'S RADIOLOGICAL PROTECTION adviser is, generally, the person responsible for the identification and disposal of material that may exhibit RADIOACTIVITY.

To assist the USER'S RADIOLOGICAL PROTECTION adviser, the following data shall be provided:

- ENERGIES and corresponding maximum ABSORBED DOSE RATES at NTD under conditions of NORMAL USE for:
 - X-RADIATION (with and without any ADDED FILTER if NORMAL USE is possible in both these states); and
 - ELECTRON RADIATION;
- dimensioned shape of the maximum GEOMETRICAL RADIATION FIELDS at NTD for X-RADIATION and ELECTRON RADIATION;
- location(s), referenced to accessible points on the RADIATION HEAD, of:
 - the front surface of the TARGET; and
 - the ELECTRON BEAM RADIATION window;
- available directions of the RADIATION BEAM;
- if a RADIATION BEAM shield is incorporated, its transmission factor at each X-RADIATION ENERGY;
- guidance and precautions regarding the identification, handling and disposal of EQUIPMENT or EQUIPMENT parts that may exhibit RADIOACTIVITY.

6.8.3 *Technical description*

a) General

Addition:

- full details of the environmental conditions and power supply required for NORMAL USE.

Additional items:

aa) SITE TEST information

The technical description shall contain the following:

- statements resulting from TYPE TESTS grade A;
- details of, and results from, TYPE TESTS grades B and C;
- SPECIFIC procedures and test conditions for SITE TESTS grade C;

NOTE 1 See Table 101 for Clause 29 SITE TEST compliance data requirements.

- instructions on how to generate a described fault condition or, if not practicable, how to generate a test signal as close as practicable to the source of the signal that would have generated it, with a statement confirming that the test signal simulates the one that would be produced in a particular fault condition;

NOTE In some cases, one test signal may simulate more than one fault condition.

- instructions on how to reset the EQUIPMENT to the NORMAL USE condition after the completion of the SITE TESTS and how to verify this condition.

NOTE 2 The person responsible for the SITE TESTS should record the results in a report which will then form part of the ACCOMPANYING DOCUMENTS; in addition, the SITE TEST report should contain at least the following:

- name and address of USER site;
- MODEL OR TYPE REFERENCE (type number) and SERIAL NUMBER of the EQUIPMENT;
- name, status and employment address of all personnel taking part in the tests, and dates of their participation;
- environmental and power supply conditions;
- the actual conditions, when test conditions, procedures or devices differ from those given by the MANUFACTURER, or where the information cannot be derived from this Particular Standard.

Compliance is checked by inspection of the technical description.

Section 2. Environmental conditions

The clauses and subclauses of this section of the General Standard apply, except as follows:

10 Environmental conditions

Addition:

NOTE See 1.1, third dash, fourth bullet, and 6.8.3a): *Addition*.

10.2.2 *Power supply*

a) EQUIPMENT shall be suitable for a power supply having:

Amendment:

Amend second dash to read as follows:

— a sufficiently low internal impedance to prevent voltage fluctuations between the on-load and off-load steady states exceeding $\pm 5\%$.

Section 3. Protection against electric shock hazards

The clauses and subclauses of this section of the General Standard apply, except as follows:

16 ENCLOSURES and PROTECTIVE COVERS

Additional item:

aa) Where the requirements of this clause are wholly or partly met by the nature of the installation, compliance test methods shall be SPECIFIED in the ACCOMPANYING DOCUMENTS.

Compliance at installation should be checked by inspection and tests; the results should be included in the SITE TEST report [see also 57.1a)].

Addition:

Table 102 — Clauses and subclauses in this Particular Standard that require the provision of information in the ACCOMPANYING DOCUMENTS, INSTRUCTIONS FOR USE and the technical description

NOTE The check reference is given as an aid for checking the availability of compliance documentation.

Check reference	ACCOMPANYING DOCUMENTS	INSTRUCTIONS FOR USE	Technical description
1		1.1	
2			1.1
3			4.1.101
4		5.4	
5	6.1d) via IEC 60601-1: 6.8.1/6.1d)		
6	6.2aa)		
7	6.8/6.8.1 (Note)		
8		6.8.2a), j)	
9			6.8.3a), aa)
10	16aa)		
11: 1, 2, 4		22.4.1a)1), a)2)	22.4.1a)4)
12		22.4.2d)	
13		22.4.3e)	
14	22.7.101		
15	28.101b)		
16			29 (see Table 101)
17	29.1.1.1c) (Note)		
18			29.1.1.1d)
19		29.1.2b)	
20: b, c, e			29.1.3b) c), e)
21			29.1.4f) (Note)
22		29.1.5d)	
23			29.1.7.3.1
24		29.1.10e)	
25: a, c		29.1.12a), c)	
26		29.1.13a)	
27		29.1.14a)	
28		29.1.15f)	
29			29.4.1b)
30			29.4.3b)
31	36		
32		52.1b)	
33			57.1a)