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INTERNATIONAL STANDARD

Medical electrical equipment –
Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

IEC 60601-2-44:2001+A1:2002(E)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

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.
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International Standard IEC 60601-2-44 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This consolidated version of IEC 60601-2-44 consists of the second edition (2001) [documents 62B/426/FDIS and 62B/437/RVD] and its amendment 1 (2002) [documents 62B/472/FDIS and 62B/478/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 2.1.

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

Annex AA forms an integral part of this standard.

Annex BB is for information only.

In this standard, the following print types are used:

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

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

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

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR IN IEC 60788: SMALL CAPITALS.

The committee has decided that the contents of the base publication and its amendment 1 will remain unchanged until 2004. At this date, the publication will be

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- withdrawn;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

A bilingual version of this publication may be issued at a later date.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

SECTION 1: GENERAL

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

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard applies to X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT SCANNERS).

It includes safety requirements for the X-RAY GENERATOR, and those where HIGH VOLTAGE GENERATORS are integrated with an X-RAY TUBE ASSEMBLY.

1.2 Object

Replacement:

The object of this standard is to establish particular requirements to ensure safety, and to specify methods for demonstrating compliance with those requirements, for CT SCANNERS.

NOTE 1 Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

NOTE 2 Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 The safety philosophy on which this standard is based is described in the introduction to the General Standard and in IEC 60513.

NOTE 4 Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the ICRP as stated in ICRP 60, 1990, paragraph 112,[1)] namely:

"(a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)

(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

[1)] ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No 1-3, 1990)*. Published by Pergamon Press.

(c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits.)"

NOTE 5 Most of the requirements on X-RAY EQUIPMENT and its sub-assemblies for protection against IONIZING RADIATION are given in the Collateral Standard IEC 60601-1-3.

This standard does, however, deal with some aspects of RADIOLOGICAL PROTECTION, mainly those that depend upon the supply, control and indication of electrical energy from the HIGH-VOLTAGE GENERATOR.

NOTE 6 It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the USER and not by the MANUFACTURER of the EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendments No. 1 (1991) and No. 2 (1995), and all Collateral Standards. The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. The changes to the text of the General Standard 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 standard.

"Addition" means that the text of this 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 standard.

Subclauses or figures which 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.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard 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 standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

1.3.101 Related International Standards

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60788:1984, *Medical radiology – Terminology*

ISO 2092:1981, *Light metals and their alloys – Code of designation based on chemical symbols*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition before 2.1:

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

NOTE Attention is drawn to the fact, that in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above a corresponding term is printed in lower case letters.

An index of defined terms used in this standard is given in annex AA.

Associated conditions qualifying the usage of certain terms are given in the additional definitions below.

In this standard unless otherwise indicated:

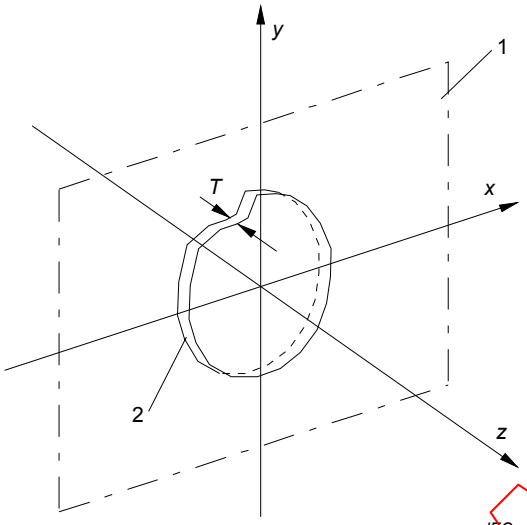
– values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;
– values of X-RAY TUBE CURRENT refer to average values.

Additional definitions:

2.101
CT SCANNER
X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT)
diagnostic X-ray system intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission data obtained at different angles. This generic type of device may include signal analysis and display equipment, PATIENT SUPPORT, support parts and ACCESSORIES

NOTE Secondary imaging processing is not included in the scope of this standard.

2.102
CT CONDITIONS OF OPERATION
all selectable parameters governing the operation of a CT SCANNER, for example NOMINAL TOMOGRAPHIC SECTION THICKNESS, PITCH FACTOR, FILTRATION, peak X-RAY TUBE VOLTAGE and either X-RAY TUBE CURRENT and LOADING TIME or CURRENT TIME PRODUCT



1 TOMOGRAPHIC PLANE
2 PHANTOM

Figure 101 – Coordinate system

2.103
DOSE PROFILE
the representation of the dose as a function of position along a line

2.104
SENSITIVITY PROFILE
the relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

2.105
TOMOGRAPHIC PLANE
the geometric plane perpendicular to the axis of rotation (see figure 101)

2.106
COMPUTED TOMOGRAPHY DOSE INDEX 100 ($CTDI_{100}$)
integral of the DOSE PROFILE produced in a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE from –50 mm to +50 mm, divided by the product of the number of TOMOGRAPHIC SECTIONS N and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T:

$$CTDI_{100} = \int_{-50\,mm}^{+50\,mm} \frac{D(z)}{N \times T} dz$$

where

$D(z)$ is the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE to air;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-RAY SOURCE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

NOTE 1 The term $CTDI_{100}$ has been introduced as a more representative value for dose than the traditional $CTDI$ integrated from –7T to +7T as defined by the FDA in 21 CFR 1020.33[1)].

NOTE 2 The dose is reported as ABSORBED DOSE to air. This is required in order to avoid present confusion, as some MANUFACTURERS of CT SCANNERS express dose values calculated as ABSORBED DOSE to air and others as ABSORBED DOSE to polymethyl-methacrylate (PMMA).

Although $CTDI_{100}$ refers to ABSORBED DOSE to air, for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA with an ionization chamber in the PHANTOM.

NOTE 3 This definition assumes that the DOSE PROFILE is centred on $z = 0$.

NOTE 4 A single axial scan is typically a 360° rotation of the X-RAY SOURCE.

2.107
CT PITCH FACTOR
in helical scanning the ratio of the PATIENT SUPPORT travel Δd along the z direction per rotation of the X-RAY SOURCE divided by the product of the NOMINAL TOMOGRAPHIC SECTION THICKNESS T and the number of TOMOGRAPHIC SECTIONS N:

$$CT\ pitch\ factor = \frac{\Delta d}{N \times T}$$

where

Δd is the PATIENT SUPPORT travel along the z direction per rotation of the X-RAY SOURCE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-RAY SOURCE.

2.108
TOMOGRAPHIC SECTION
volume over which TRANSMISSION data of X-RADIATION are collected in a single axial scan

NOTE In a CT SCANNER with multiple detector elements along the z-axis, it is the volume over which data are collected by a single acquisition channel (selected grouping of elements) and not the total volume irradiated.

1) See bibliography.

2.109
TOMOGRAPHIC SECTION THICKNESS
FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE taken at the iso-centre of a TOMOGRAPHIC SECTION

2.110
NOMINAL TOMOGRAPHIC SECTION THICKNESS
in CT SCANNERS the TOMOGRAPHIC SECTION THICKNESS which is selected and indicated on the CONTROL PANEL

NOTE In helical scanning the thickness of a reconstructed image depends on the helical reconstruction algorithm and pitch, and hence this thickness may not equal the NOMINAL TOMOGRAPHIC SECTION THICKNESS. The thickness of the reconstructed image may be indicated or selected prior to the helical scan.

3 General requirements

This clause of the General Standard applies except as follows:

3.1 *Addition:*

CT SCANNERS shall be designed so as not to deliver a voltage higher than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE ASSEMBLY.

5 Classification

This clause of the General Standard applies except as follows:

5.1 *Replacement:*

HIGH VOLTAGE GENERATORS in CT SCANNERS shall be CLASS I EQUIPMENT or INTERNALLY POWERED EQUIPMENT.

5.6 *Replacement:*

Unless otherwise specified, CT SCANNERS or sub-assemblies thereof shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS; see also 6.1 m) and 6.8.101.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

g) *Connection to the supply*

Addition:

For CT SCANNERS that are specified to be permanently installed, the information required in 6.1 g) of the General Standard may be stated only in the ACCOMPANYING DOCUMENTS.

m) *Mode of operation*

Replacement:

The mode of operation – where appropriate, together with maximum permissible ratings – shall be stated in the ACCOMPANYING DOCUMENTS; see 6.8.101.

p) *Output*

Replacement:

This subclause of the General Standard does not apply.

t) *Cooling conditions*

Addition:

The cooling requirements for the safe operation of a CT SCANNER, or a sub-assembly thereof, shall be indicated in the ACCOMPANYING DOCUMENTS, including as appropriate the maximum heat dissipation.

6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition after the first paragraph:

For CT SCANNERS, the colours to be used for indicator lights shall be as follows:

– the colour green shall be used at the CONTROL PANEL to indicate the state from which one further action leads to the LOADING STATE; see 29.1.101.1 a);

– the colour yellow shall be used at the CONTROL PANEL to indicate the LOADING STATE; see 29.1.101.1 b).

NOTE The colours of indicator lights need to be chosen according to the message to be given. Thus, the same operational state of an EQUIPMENT can have simultaneous indications in different colours depending upon the place of indication, for example green at the CONTROL PANEL and red at the entrance to the EXAMINATION ROOM.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

Electric output data shall be stated in the INSTRUCTIONS FOR USE in terms of LOADING FACTORS as described in 6.8.2 a) 1) to 6.8.2 a) 4).

For CT SCANNERS in which part of the HIGH-VOLTAGE GENERATOR is integrated with the X-RAY TUBE ASSEMBLY (for example X-RAY TUBE HEADS) the stated values shall refer to the complete device.

The following combinations and data shall be stated:

1) The corresponding NOMINAL X-RAY TUBE VOLTAGE together with the highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE.
2) The corresponding highest X-RAY TUBE CURRENT together with the highest X-RAY TUBE VOLTAGE, obtainable from the HIGH-VOLTAGE GENERATOR when operating at that X-RAY TUBE CURRENT.
3) The corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power.
4) The NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts which the HIGH-VOLTAGE GENERATOR can deliver, for a LOADING TIME of 4 s at an X-RAY TUBE VOLTAGE of 120 kV, or if these values are not selectable, with an X-RAY TUBE VOLTAGE nearest to 120 kV and the value of LOADING TIME nearest to but not less than 4 s.

The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME which are used in the CT SCANNER.

6.8.3 Technical description

a) *General*

Addition:

The technical description shall contain information about the combination or, if necessary, the combinations of sub-assemblies and ACCESSORIES of a CT SCANNER.

NOTE Attention is drawn to the usefulness in the technical description of

– data and essential characteristics to determine the ratings of an earth leakage circuit breaker, or

– indication of the types of earth leakage circuit breakers which can be used with the HIGH-VOLTAGE GENERATOR.

Addition:

6.8.101 Reference to ACCOMPANYING DOCUMENTS

Clauses and subclauses of this standard in which additional requirements concerning the content of ACCOMPANYING DOCUMENTS are given:

Mode of operation and specified LOADINGS ..... 5.6 and 6.1 m)
Connection to the supply ..... 6.1 g)
Protection against STRAY RADIATION 29.208

APPARENT RESISTANCE OF SUPPLY MAINS 10.2.2
Cooling conditions ..... 6.1 t)
Electric output data of the HIGH-VOLTAGE GENERATOR and LOADING FACTORS ..... 6.8.2 a) and 50.101
Suitable combinations for compliance test ..... 6.8.3 a) and 50.1
Earth leakage circuit breaker ..... 6.8.3 a)
Compliance with this standard 6.8.102
Central connection point PROTECTIVE EARTH CONDUCTOR 19.3

6.8.102 Statement of compliance

If for a CT SCANNER, or a sub-assembly thereof, compliance with this standard is to be stated, the statement shall be stated in the ACCOMPANYING DOCUMENTS:

CT SCANNER... [++)] IEC 60601-2-44: 2001

[++)] MODEL OR TYPE REFERENCE

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

SECTION 2: ENVIRONMENTAL CONDITIONS

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

10 Environmental conditions

This clause of the General Standard applies except as follows:

10.2.2 Power supply

Item a)

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of a CT SCANNER if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ±2 % of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems may be derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

A CT SCANNER is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

15 Limitation of voltage and/or energy

This clause of the General Standard applies except as follows:

Addition:

aa) Detachable high-voltage cable connections to the X-RAY TUBE ASSEMBLY shall be designed so that the use of TOOLS is required to disconnect them or to remove their PROTECTIVE COVERS.

Compliance is checked by inspection.

bb) Provision shall be made to prevent the appearance of an unacceptably high-voltage in the MAINS PART or in any other low-voltage circuit.

NOTE This may be achieved for example:

– by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between high-voltage and low-voltage circuits;

– by provision of a voltage-limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance is checked by inspection of design data and construction.

16 ENCLOSURES and PROTECTIVE COVERS

This clause of the General Standard applies except as follows:

Addition:

NOTE Requirements concerning the resistance and earthing of a flexible conductive screen of high-voltage cables connected to X-RAY TUBE ASSEMBLIES are given in IEC 60601-2-28.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

19.3 Allowable values

Addition:

FOR CT SCANNERS the column on TYPE B and the rows on EARTH LEAKAGE CURRENT in NORMAL CONDITION and SINGLE FAULT CONDITION and on ENCLOSURE LEAKAGE CURRENT in NORMAL CONDITION of table IV, including the notes, of the General Standard apply.

The allowable values of EARTH LEAKAGE CURRENT are permitted for each sub-assembly of CT SCANNERS that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and permanently installed.

A fixed and permanently installed central PROTECTIVE EARTH TERMINAL may be provided inside the outer ENCLOSURE or cover of the CT SCANNER. If other sub-assemblies or ASSOCIATED EQUIPMENT are connected to the PROTECTIVE EARTH TERMINAL, the EARTH LEAKAGE CURRENT between such a central connection point and the external protective system may exceed the allowable values for any one of the single devices connected.

NOTE The limitation of the EARTH LEAKAGE CURRENTS within the environment of a CT SCANNER is intended to ensure that ACCESSIBLE PARTS do not become live and to prevent interference in other electrical equipment.

The provision of a central PROTECTIVE EARTH TERMINAL is acceptable, as for fixed and PERMANENTLY INSTALLED EQUIPMENT the interruption of the PROTECTIVE EARTH CONDUCTOR is not considered to be a SINGLE FAULT CONDITION. However, in such cases, adequate information on the combination of ASSOCIATED EQUIPMENT needs to be provided in accordance with 6.8.3 a).

Compliance is checked by inspection.

20 Dielectric strength

This clause of the General Standard applies except as follows:

20.3 Values of test voltages

Addition:

The dielectric strength of the electrical insulation of high-voltage circuits shall be sufficient to withstand the test voltages for the durations given in 20.4 a).

The test shall be made without an X-RAY TUBE connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the HIGH-VOLTAGE GENERATOR.

If the HIGH-VOLTAGE GENERATOR can only be tested with the X-RAY TUBE connected, the test voltage may be lower but shall not be less than 1,1 times the NOMINAL X-RAY TUBE VOLTAGE of the HIGH-VOLTAGE GENERATOR.

20.4 Tests

Item *a)*

Addition:

The high-voltage circuits of HIGH-VOLTAGE GENERATORS or sub-assemblies thereof are tested by applying a test voltage of 50 % of its final value according to 20.3 and raising it over a period of 10 s or less to the final value, which then is maintained for 3 min.

If during the dielectric strength test there is a risk of overheating a transformer or associated circuitry under test, it is permitted to carry out the test at a higher supply frequency or to supply the test voltage to the secondary side by another generator.

Item *d)*

Replacement:

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept to 100 % to 105 % of the value required.

Item *f)*

Addition:

During the dielectric strength test of HIGH-VOLTAGE GENERATORS slight corona discharges in the high-voltage circuit are to be disregarded if they cease when the test voltage is lowered to 1,1 times the voltage to which the test condition is referred.

Item *l)*

Addition:

The test voltage for the dielectric strength testing of stator and stator circuits used for the operation of the rotating ANODE of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

Additional item aa):

1) *HIGH-VOLTAGE GENERATORS or sub-assemblies thereof that are integrated with an X-RAY TUBE ASSEMBLY are to be tested with an appropriately loaded X-RAY TUBE.*
2) *If the dielectric strength test is performed with an X-RAY TUBE connected and the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures are to be taken to ensure that the values lie within the limits required in 20.4 d).*

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

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

22 Moving parts

Subclause 22.4 of IEC 60601-2-32 applies except as follows:

Addition:

22.4.101 Gantry and PATIENT SUPPORT

a) General

1) Interruption or failure of powered movements or of the SUPPLY MAINS shall cause any parts in motion to be stopped within the limits given in items b) and c). The maximum value of distance and angle for each stopping condition shall be given in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by interruption of the SUPPLY MAINS to powered movements and measurement of stopping distances. These tests shall be performed with a PATIENT-equivalent mass of 135 kg distributed evenly over the PATIENT SUPPORT.

2) When a part is provided with one or several devices designed to reduce, in NORMAL USE, the risk of collision with the PATIENT, the operation and limitations of each device shall be described in the INSTRUCTIONS FOR USE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

3) Where there is a possibility that a failure of a powered movement during NORMAL USE of the EQUIPMENT might result in the PATIENT being trapped, controls and switches shall be provided to permit the release of the PATIENT. These means shall be described in the INSTRUCTIONS FOR USE and on a label on the EQUIPMENT when a deliberate action is required.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

b) Tilting of the gantry

When the emergency stop control is actuated, the gantry tilt shall stop within an angle of 0,5°.

Compliance is checked by inspection.

c) Linear movements of the PATIENT SUPPORT

When the emergency stop control is actuated, the PATIENT SUPPORT shall stop within a distance of 10 mm.

Compliance is checked by inspection.

22.4.102 Operation of EQUIPMENT movements from inside the RADIATION room

Any motorized movements of equipment parts which may cause physical injury to the PATIENT shall be controlled by continuous deliberate action by the OPERATOR.

The control shall be located close to the PATIENT SUPPORT so that the OPERATOR can continuously observe the PATIENT and thus avoid possible injury to the latter and be positioned in such a way that it cannot easily be touched by the PATIENT.

22.4.103 Operation of EQUIPMENT movements from outside the RADIATION room

Any motorized movements of equipment parts which may cause physical injury to the PATIENT shall be controlled by continuous deliberate action by the OPERATOR. Those movements which are part of a pre-programmed scanning protocol are exempt from this requirement.

Subclause 22.7 of IEC 60601-1 applies except as follows:

Addition:

22.7.101 Emergency stop of motorized movements

Readily identifiable and accessible controls and switches shall be provided in hard-wired circuits near to, or on, the PATIENT SUPPORT and/or gantry, for emergency stopping of all motorized movements by interruption of the SUPPLY MAINS to the movement system. When operated, any movement shall stop within the limits given in 22.4.101. These controls and switches shall be positioned in such a way that they cannot be operated accidentally.

Similar controls shall also be provided near to, or on, any remote CONTROL PANEL from which movements can be actuated.

The time to effect the disconnection of the SUPPLY MAINS after initiation by the controls and switches shall not exceed 0,5 s.

NOTE The controls provided for emergency stopping of all motorized movements by interruption of the SUPPLY MAINS to the movement system should also terminate LOADING as described in 29.1.101. Both controls may be the same emergency stop button.

Compliance is checked by inspection and measurement of stopping distances and disconnection time.

27 Pneumatic and hydraulic power

This clause of the General Standard applies except as follows:

Addition:

27.101 Variations of PRESSURE in PRESSURE-powered movements of CT SCANNERS

If a hazardous situation can arise from a change in the PRESSURE of a system used to provide power for movements, all movements shall stop within the limits specified in 22.4.101.

Compliance is checked by simulation of a fault condition, the operation of protective devices and measurement of stopping distances.

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

29 X-RADIATION

This clause of the General Standard applies except as follows:

Additional subclauses:

29.1.101 Emergency termination of X-RADIATION

Readily identifiable and accessible means shall be provided in hard-wired circuits near to, or on, the PATIENT SUPPORT and/or the gantry for emergency interruption to terminate LOADING.

NOTE The means provided for emergency interruption of all SUPPLY MAINS to terminate LOADING should also stop all movements as described in 22.4.101 b), 22.4.101 c) and 22.7.101. Both means may be the same emergency stop button.

Compliance is checked by the appropriate functional tests.

29.1.101.1 Indication of operational states

a) READY STATE

Visible indication shall be provided on the CONTROL PANEL indicating the state when one further actuation of a control from that CONTROL PANEL will initiate the LOADING of the X-RAY TUBE.

If this state is indicated by means of a single-function indicator light, the colour green shall be used; see 6.7 a).

Means shall be provided for a connection to enable this state to be indicated remotely from the CONTROL PANEL. This requirement does not apply for MOBILE EQUIPMENT.

b) LOADING STATE

The LOADING STATE shall be indicated by a yellow indicator light on the CONTROL PANEL of the CT system; see 6.7 a).

Compliance is checked by inspection and by the appropriate functional tests.

29.1.101.2 Limitation of RADIATION output

a) Means shall be provided to limit the electric energy to be delivered by the use of fixed or pre-selected combinations of suitable LOADING FACTORS and modes of operation.

During IRRADIATION, the OPERATOR shall be able to terminate the LOADINGS at any time, but means may be provided to acquire up to one additional rotation of the X-RAY SOURCE.

b) Any control by which the LOADING of an X-RAY TUBE can be initiated shall be safeguarded against unintended actuation.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.101.3 Connection of external INTERLOCKS

CT SCANNERS shall be provided with connections for external INTERLOCKS that can be positioned remotely from the CT SCANNER and can cause the X-RAY GENERATOR to stop emitting X-RADIATION and can prevent the X-RAY GENERATOR from starting to emit X-RADIATION.

The diagnostic and interventional methods performed on a CT-SCANNER will in practically all cases expose the PATIENT as well as the OPERATOR to a significantly higher dose when external INTERLOCKS are activated, as the radiological examination may have to be repeated. Also the interruption of an interventional procedure may cause an additional risk to the PATIENT. Such INTERLOCKS should therefore only be applied when unavoidable, e.g. when required by other regulations.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.102 Dose statements and test equipment

29.1.102.1 Dose statements

The following dose information shall be obtained by using the dosimetry PHANTOM for COMPUTED TOMOGRAPHY. For any CT SCANNER designed to image both the head and body, separate dose information shall be provided for each application in the ACCOMPANYING DOCUMENTS. All dose measurements shall be performed with the PHANTOM specified in 29.1.102.2 placed on the PATIENT SUPPORT without additional attenuating material present. This dosimetry PHANTOM shall be centred in the scan field and on the axis of rotation of the scanner.

The following information shall be given in the ACCOMPANYING DOCUMENTS:

a) The $CTDI_{100}$ and the corresponding CT CONDITIONS OF OPERATION at the following locations in the dosimetry PHANTOM specified in 29.1.102.2:

   1) Along the axis of rotation of the PHANTOM ($CTDI_{100(centre)}$).

   2) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM, with the PHANTOM positioned so that the $CTDI_{100}$ is the maximum obtainable at this depth.

   3) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM at positions 90°, 180° and 270° from the position in item a) 2) of this subclause. The CT CONDITIONS OF OPERATION shall be the typical values suggested by the MANUFACTURER. The location of the position where the $CTDI_{100}$ is maximum as specified in item a) 2) of this subclause shall be given by the MANUFACTURER with respect to the housing of the scanning mechanism or other readily identifiable part of the CT SCANNER in such a manner as to permit placement of the dosimetry PHANTOM in this orientation.

   4) $CTDI_{100\ (peripheral)}$ is the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery according to 29.1.102.1 a) 2) and 3).

b) The $CTDI_{100}$ in the centre location of the dosimetry PHANTOM for each selectable CT CONDITION OF OPERATION that varies either the rate or duration of IRRADIATION or the NOMINAL TOMOGRAPHIC SECTION THICKNESS. This $CTDI_{100}$ shall be presented as a value that is normalized to the $CTDI_{100}$ in the centre location of the dosimetry PHANTOM from item a) of this subclause, with the $CTDI_{100}$ of item a) of this paragraph having a value of 1. As a single CT CONDITION OF OPERATION is changed, all other independent CT CONDITIONS OF OPERATION shall be maintained at the typical values described in item a) of this subclause. These data shall encompass the range of each CT CONDITION OF OPERATION stated by the MANUFACTURER as appropriate. When more than three selections of a CT CONDITION OF OPERATION are available, the normalized $CTDI_{100}$ shall be provided, at least for the minimum, maximum and one mid-range value of the CT CONDITION OF OPERATION.

c) The $CTDI_{100}$ at the location coincident with the maximum $CTDI_{100}$ at 10 mm interior to the surface of the dosimetry PHANTOM for each selectable peak X-RAY TUBE VOLTAGE. When more than three selections of the peak X-RAY TUBE VOLTAGE are available, the normalized $CTDI_{100}$ shall be provided, at least for the minimum, maximum and one mid-range value of the peak X-RAY TUBE VOLTAGE. The $CTDI_{100}$ shall be presented as a value that is normalized to the maximum $CTDI_{100}$ located at 10 mm interior to the surface of the dosimetry PHANTOM from item a) above, with the $CTDI_{100}$ of item a) above having a value of 1.

d) A statement of the maximum deviation from the values given according to items a), b) and c). Deviation of values shall not exceed these limits.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

29.1.102.2 Dosimetry PHANTOM

The dosimetry PHANTOM shall consist of PMMA cylinders of diameter 160 mm for head techniques and 320 mm for body techniques. The length of the PHANTOM shall be at least 140 mm. The PHANTOM shall be longer than the sensitive volume of the RADIATION DETECTOR used for the measurements. The PHANTOM shall contain holes just large enough to accept the RADIATION DETECTOR. These holes shall be parallel to the axis of symmetry of the PHANTOM and the centres of the holes shall be located at the centre and 10 mm below the surface of the PHANTOM at 90° intervals.

For the holes not used during a measurement, properly fitting insert parts of the same material as the PHANTOM shall be used.

29.1.103 Dose information

29.1.103.1 DOSE PROFILE

A graphical presentation of the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE measured in the centre location of the head-dosimetry PHANTOM and body-dosimetry PHANTOM shall be given in the ACCOMPANYING DOCUMENTS for each selectable NOMINAL TOMOGRAPHIC SECTION THICKNESS. When more than three NOMINAL TOMOGRAPHIC SECTION THICKNESSES are available, the information shall be provided for at least the minimum, maximum and one mid-range value of NOMINAL TOMOGRAPHIC SECTION THICKNESS. The DOSE PROFILE shall be presented on the same graph and to the same scale as the corresponding SENSITIVITY PROFILE required by 29.1.103.2.

29.1.103.2 SENSITIVITY PROFILE

A graphical presentation of the SENSITIVITY PROFILE at the location corresponding to the centre location of the dosimetry PHANTOM shall be given in the ACCOMPANYING DOCUMENTS for each NOMINAL TOMOGRAPHIC SECTION THICKNESS for which the DOSE PROFILE is given according to 29.1.103.1.

29.1.103.3 Weighted $CTDI_{100}$

The weighted $CTDI_{100}$ ($CTDI_w$) is defined as

$$CTDI_W = \frac{1}{3} CTDI_{100(centre)} + \frac{2}{3} CTDI_{100(peripheral)}$$

see 29.1.102.1 a), items 1) and 4).

29.1.103.4 Volume $CTDI_w$ ($CTDI_{vol}$)

The volume $CTDI_W$ ($CTDI_{vol}$) describes the average dose over the total volume scanned for the selected CT CONDITIONS OF OPERATION.

The $CTDI_{vol}$ is defined as follows:

a) for axial scanning

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_w$$

where

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-RAY SOURCE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

Δd is the PATIENT SUPPORT travel in z-direction between consecutive scans.

b) for helical scanning

$$CTDI_{vol} = \frac{CTDI_w}{CT\ pitch\ factor}$$

c) for scanning without pre-programmed movement of the PATIENT SUPPORT

$$CTDI_{vol} = n \times CTDI_w$$

where n is equal to the maximum number of pre-programmed rotations.

The value for $CTDI_{vol}$ expressed in milligray (mGy) shall be displayed on the CONTROL PANEL, reflecting the type of examination selected, head or body, and the CT CONDITIONS OF OPERATION.

When the X-RAY TUBE CURRENT varies within a scan, the pre-programmed LOADING FACTORS that determine the maximum possible $CTDI_{vol}$ shall be used to calculate the $CTDI_{vol}$.

If the number of rotations is not pre-programmed, the $CTDI_{vol}$ per second shall be displayed expressed in milligray per second (mGy/s) and the accumulated $CTDI_{vol}$ shall be displayed, expressed in milligray (mGy) during the examination.

NOTE 1 The displayed $CTDI_{vol}$ given by the MANUFACTURER may be a representative figure for that model and not the value measured on the particular CT SCANNER

NOTE 2 The definition of $CTDI_{vol}$ in section c) will likely overestimate the actual dose since the maximum number of pre-programmed rotations is applied, but is used as a conservative estimation of dose to help assure PATIENT protection from skin radiation injury.

NOTE 3 The manual movement of the PATIENT SUPPORT is included under c).

Compliance is checked by inspection.

29.1.103.5 Geometric efficiency in z-direction

The geometric efficiency in *z*-direction is the integral of the DOSE PROFILE along the *z*-direction, integrated over the range subtended by the detector elements used during acquisition, expressed as percentage of the total integral of the DOSE PROFILE in the *z*-direction. The range is defined by the geometry of the selected detector elements and by the selected post-PATIENT collimation used during acquisition, which ever is less. The DOSE PROFILE shall be measured without any object in the X-RAY BEAM. For those slices with an efficiency of less than 70 %, the actual geometrical efficiency in *z*-direction shall be displayed on the CONTROL PANEL.

Compliance is checked by inspection.

29.1.104 FOCAL SPOT TO SKIN DISTANCE

CT SCANNERS shall be constructed such that the minimum FOCAL SPOT TO SKIN DISTANCE is at least 15 cm.

Compliance is checked by inspection.

29.1.105 Safety measures against excessive X-RADIATION

a) Means shall be provided to terminate the LOADING automatically by de-energizing the RADIATION SOURCE in the event of timer failure. Such a termination shall occur within an interval that limits the total scan time to not more than the lesser of 110 % of the preset value or one extra rotation of the X-RAY SOURCE ASSEMBLY through the use of either a back-up timer or devices which monitor the EQUIPMENT function. A visible indication of termination shall be provided to the OPERATOR.

b) Means shall be provided to terminate the LOADING automatically by de-energizing the RADIATION SOURCE in the event of EQUIPMENT failure affecting data collection within a specified period. Such a termination shall occur within 1 s of such a failure. A visible indication of termination shall be provided to the OPERATOR.

c) Means shall be provided so that the OPERATOR can terminate the LOADING at any time during a scan, or series of scans under X-RAY EQUIPMENT control, of greater than 0,5 s duration.

d) When LOADING has been terminated by circumstances noted under a), b) and c) above, resetting of the CT CONDITIONS OF OPERATION shall be required prior to the initiation of another scan.

e) When more than one scan is programmed in the same TOMOGRAPHIC PLANE there shall be a warning on the OPERATOR's console that this mode has been selected and the OPERATOR shall confirm that this is to occur before continuing with the scan series.

f) Any data acquired prior to interrupting the LOADING of a helical scan series should be available for image reconstruction when LOADING has been interrupted by whatever cause.

Compliance is checked by inspection and tests.

29.1.106 Control and indication of operable states

29.1.106.1 Visual indication

The CT CONDITIONS OF OPERATION to be used during a scan series shall be indicated prior to the initiation of a scan or scan series. On EQUIPMENT having all or some of these CT CONDITIONS OF OPERATION at fixed values, this requirement may be met by permanent markings. Indication of the CT CONDITIONS OF OPERATION shall be visible from any position from which the READY STATE can be initiated.

Compliance is checked by inspection.

29.1.106.2 Beam-on status indicator

When, and only when, RADIATION is produced, visible indication shall be provided on the CONTROL PANEL from which the X-RADIATION is actuated and on or near the housing of the scanning mechanism. Indicators at or near the housing of the scanning mechanism shall be visible from any point external to the PATIENT opening where insertion of any part of the human body into the PRIMARY RADIATION BEAM is possible.

Compliance is checked by inspection.

The additional subclauses of clause 29 of the Collateral Standard IEC 60601-1-3 apply, except as follows:

29.201 RADIATION QUALITY

This subclause 29.201 of the Collateral Standard IEC 60601-1-3 applies, except as follows:

Replacement of the NOTE:

NOTE 29.201.3 to 29.201.9 relate to the need for the RADIATION QUALITY of X-RAY BEAMS to be appropriate for producing the intended diagnostic images without administering unnecessarily high ABSORBED DOSES to the PATIENT. The required measures address RADIATION QUALITY in terms of both FILTRATION for X-RAY SOURCE ASSEMBLIES and of first HALF-VALUE LAYER in CT SCANNERS.

Addition:

For CT SCANNERS with shaped X-ray FILTERS measurements of RADIATION QUALITY shall be performed in the centre of the TOMOGRAPHIC PLANE.

It is to be assumed that for a CT SCANNER the PERCENTAGE RIPPLE of the HIGH-VOLTAGE GENERATOR does not influence the quality of the images.

29.201.1 Limitation of operating voltage range in dental applications

This subclause of the Collateral Standard IEC 60601-1-3 is not applicable.

29.201.5 TOTAL FILTRATION in X-RAY EQUIPMENT

Replacement:

In addition to the FILTRATION addressed in 29.201.3 and 29.201.4, fixed ADDED FILTERS shall be used such that, for all configurations in NORMAL USE, the first HALF-VALUE LAYERS attained in the X-RAY BEAM incident to the PATIENT shall not be less than the minimum permissible values given in table 101.

Table 101 – HALF-VALUE LAYERS in CT SCANNERS

X-RAY TUBE VOLTAGE (see note 1) kV	Minimum permissible first HALF-VALUE LAYER (see note 2) mm Al
<60	See note 3
60	1,9
70	2,1
80	2,4
90	2,7
100	3,0
110	3,4
120	3,8
130	4,2
140	4,6
>140	see note 3

NOTE 1 HALF-VALUE LAYERS for intermediate voltages are to be obtained by linear interpolation.

NOTE 2 The values correspond to a TOTAL FILTRATION of 2,5 mm Al.

NOTE 3 Linear extrapolation is to be used here.

Compliance with the HALF-VALUE LAYER requirement shall be maintained for all selectable values of ADDITIONAL FILTRATION.

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS and by the test described in 29.201.9.

29.201.9 Test for HALF-VALUE LAYER

Replacement:

Measure the first HALF-VALUE LAYER under NARROW BEAM CONDITIONS for all selectable values of the X-RAY TUBE VOLTAGE. If there are more than three selectable values of X-RAY TUBE VOLTAGE, HALF-VALUE LAYERS shall be measured for at least the minimum, maximum and one mid-range value of the X-RAY TUBE VOLTAGE.

The material of these layers shall be aluminium of a purity of at least 99,9 % (designated by Al 99,9 according to ISO 2092).

Compliance is checked by inspection.

29.202 Limitation and indication of the extent of the X-RAY BEAM

Subclauses 29.202.4 to 29.202.9 of the Collateral Standard IEC 60601-1-3 do not apply. The following subclause is added:

29.202.101 Indication and position of the TOMOGRAPHIC SECTION

a) A preview image shall be provided on which the OPERATOR may set up the TOMOGRAPHIC SECTIONS to be taken. The reference lines indicating these sections shall not differ from the true positions by more than 2 mm with the gantry in vertical position.

b) A LIGHT FIELD shall be provided for marking the TOMOGRAPHIC SECTION. The LIGHT FIELD shall be visible under ambient light conditions of up to 500 lx. The width of the LIGHT FIELD shall not exceed 3 mm, measured in the centre of the gantry opening. The centre of the TOMOGRAPHIC SECTION shall be within 2 mm of the centre of the LIGHT FIELD. If more than one TOMOGRAPHIC SECTION is acquired at a time, the ACCOMPANYING DOCUMENTS shall describe the position of the LIGHT FIELD in reference to the TOMOGRAPHIC SECTIONS. If additional light fields are provided for reference purposes, their accuracy shall be defined in the ACCOMPANYING DOCUMENTS.

c) For motions of the PATIENT SUPPORT beginning at a typical starting position, continuing to a position which is the lesser of the maximum selectable scan increment or 30 cm and returning to the starting position, the deviation of the scan increment shall not exceed 1 mm. This test shall be performed with a load of at least 135 kg evenly distributed across the PATIENT SUPPORT. Measurements of actual versus indicated scan increment may be taken anywhere along the travel.

Compliance is checked by inspection.

29.203 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

Subclause 29.203 of IEC 60601-1-3 does not apply.

29.204.2 Statement of reference LOADING conditions

Replacement:

The ACCOMPANYING DOCUMENTS for all X-RAY TUBE ASSEMBLIES and X-RAY TUBE sub-assemblies shall state the values of CT CONDITIONS OF OPERATION that would, if applied at the NOMINAL X-RAY TUBE VOLTAGE, correspond to the MAXIMUM CONTINUOUS HEAT DISSIPATION.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

29.206 ATTENUATION of the X-RAY BEAM

Subclause 29.206 of the Collateral Standard IEC 60601-1-3 does not apply.

29.208 Protection against STRAY RADIATION

Replacement

STRAY RADIATION measurements shall be given for those LOADING FACTORS which result in the maximum local dose per CURRENT TIME PRODUCT. These LOADING FACTORS should at least include the highest selectable X-RAY TUBE VOLTAGE. A cylindrical PHANTOM of TISSUE EQUIVALENT MATERIAL (e.g. water or PMMA) with a diameter of 320 mm and a length of 140 mm to 200 mm shall be used for the measurements. It shall be positioned in the centre of rotation of the CT SCANNER. The PHANTOM shall be centered on the TOMOGRAPHIC PLANE. The measurement results may be averaged over a volume of 500 cm^3 of which no principal linear dimension exceeds 200 mm.

Addition:

29.208.101 Statements in the ACCOMPANYING DOCUMENTS

STRAY RADIATION measurements shall be given measured in the horizontal plane which is at the height of the centre of rotation of the CT SCANNER. The region of measurement shall include the region of a rectangle defined as follows: the side which is parallel with the axis of rotation is at least 3 m long with its centre at the position of the scan plane and extends as far as necessary to include the region of the PATIENT SUPPORT; the side which is perpendicular to the axis of rotation is at least 3 m long with its centre at the position of the axis of rotation. Measurements shall be provided at least at every 50 cm in both directions. Information regarding the PHANTOM shall be provided in the ACCOMPANYING DOCUMENTS.

The unit of measurement shall be AIR KERMA per mAs applied to the X-RAY TUBE during NORMAL USE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

36 Electromagnetic compatibility

This clause of the General Standard applies except as follows:

Replacement:

IEC 60601-1-2 shall be applicable.

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

42 Excessive temperatures

This clause of the General Standard applies except as follows:

42.1 *Addition:*

Restrictions on allowable maximum temperature for parts in contact with oil shall not apply to parts wholly immersed in oil.

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

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

50 Accuracy of operating data

This clause of the General Standard applies except as follows:

Addition:

50.101 Accuracy of radiation output

The MANUFACTURER shall provide with the ACCOMPANYING DOCUMENTS information regarding the accuracy of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and linearity of RADIATION output.

Compliance is checked by inspection.

50.102 Accuracy of recorded examination data

a) When a RADIOGRAM of the preview image is provided (as described in 29.202.103 a)) the position of each selected TOMOGRAPHIC SECTION shall be clearly indicated on the RADIOGRAM.

   The indication of the position of the TOMOGRAPHIC SECTIONS shall be accurate within 2 mm.

b) In NORMAL USE the information indicating the orientation of the displayed image with respect to the PATIENT shall be displayed with each image.

Compliance is checked by inspection.

50.102.1 Indication of electric and RADIATION output

Adequate information shall be available to the OPERATOR, before, during and after the LOADING of an X-RAY TUBE, about fixed, permanently or semi-permanently preselected or otherwise predetermined LOADING FACTORS or modes of operation so as to enable the OPERATOR to preselect appropriate conditions for the IRRADIATION and subsequently to obtain data necessary for the estimation of the ABSORBED DOSE received by the PATIENT.

The units of indication shall be as follows:

– for X-RAY TUBE VOLTAGE: kilovolts;
– for X-RAY TUBE CURRENT: milliamperes;
– for LOADING TIME: seconds;
– for CURRENT TIME PRODUCT: milliampere-seconds.

Compliance is checked by inspection.

50.102.2 Shortened indication

a) For CT SCANNERS operating with one or more fixed combinations of LOADING FACTORS, the indication on the CONTROL PANEL may be confined to the value of only one of the significant LOADING FACTORS for each combination, for example the value of X-RAY TUBE VOLTAGE.

In this case the indication of the corresponding values of the other LOADING FACTORS in each combination shall be given in the INSTRUCTIONS FOR USE.

In addition, these values shall be listed in a form suitable to be displayed at a prominent location on or near the CONTROL PANEL.

b) For CT SCANNERS operating with fixed combinations of semi-permanently preselectable LOADING FACTORS, the indication on the CONTROL PANEL may be confined to a clear reference to the identity of each combination.

In this case, provisions shall be made to enable:

– the values of each combination of semi-permanently preselected LOADING FACTORS set at the time of installation to be recorded in the INSTRUCTIONS FOR USE; and
– the values to be listed in a suitable form to be displayed at a prominent location on or near the CONTROL PANEL.

Compliance is checked by inspection.

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

Replacement:

Protection against incorrect output is considered to exist by compliance with 29.1.104.

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.