INTERNATIONAL STANDARD

IEC 60601-2-44

First edition
1999-02

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-44:
Règles particulières de sécurité pour les équipements à rayonnement X de tomodensitométrie

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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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

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

FDIS	Report on voting
62B/360/FDIS	62B/364/RVD

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table.

Annex AA forms an integral part of this standard.

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: small roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS PARTICULAR STANDARD OR IN IEC 60788: SMALL CAPITALS.

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

INTRODUCTION

The relationship of this Particular Standard with IEC 60601-1 (including the amendments) and the Collateral Standards is explained in 1.3.

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 does not cover the safety requirements for HV-generators which will be the subject of another standard.

1.2 Object

Replacement:

The object of this standard is to establish requirements for safe operation of CT SCANNERS in as far as those requirements have not yet been specified in the General Standard, the Collateral Standards or other Particular Standards.

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 1 (1991) and 2 (1995), and any Collateral Standard.

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 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 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 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 Particular 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 Particular Standard.

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

1.3.101 Related international standards

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

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 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

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:

2.101 Definitions

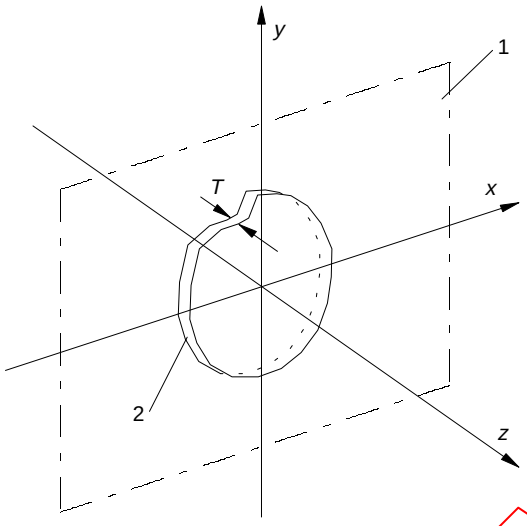
In this Particular Standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in the General Standard, in this standard or in IEC 60788.

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

Additional definitions:

2.101.1
CT SCANNER
X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY

2.101.2
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

IEC 210/99

Figure 101 – Coordinate system

2.101.3
DOSE PROFILE
representation of the dose as a function of position along a line

2.101.4
SENSITIVITY PROFILE
relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

2.101.5
TOMOGRAPHIC PLANE
geometric plane defined by the FOCAL SPOT and perpendicular to the axis of rotation; see figure 101

2.101.6
COMPUTED TOMOGRAPHY DOSE INDEX 100 ($CTDI_{100}$)
integral of the DOSE PROFILE 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 produced in a single 360° rotation of the RADIATION SOURCE and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T in a single rotation of the RADIATION SOURCE

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

where

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

N is the number of TOMOGRAPHIC SECTIONS produced in a single rotation of the RADIATION 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 Ch. I § 1020.33.

NOTE 2 – Dose is calculated 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).

NOTE 3 – When the RADIATION SOURCE rotation is limited to less than 360°, the $CTDI_{100}$ should be scaled accordingly.

NOTE 4 – This definition assumes that the DOSE PROFILE is centred on $z = 0$ and that for CT SCANNERS, which acquire two or more TOMOGRAPHIC SECTIONS in one rotation, the increment between adjacent scans is $N \times T$ and for helical scans the CT PITCH FACTOR is equal to 1.

2.101.7
CT PITCH FACTOR
ratio of the PATIENT SUPPORT travel in the horizontal direction per rotation of the X-RAY TUBE divided by the product of the number N of TOMOGRAPHIC SECTIONS irradiated simultaneously by the X-RAY TUBE, and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T.

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

where:

Δd is the PATIENT SUPPORT travel in horizontal direction;

N is the number of TOMOGRAPHIC SECTIONS produced by a single rotation of the X-RAY TUBE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

2.101.8
TOMOGRAPHIC SECTION
volume of an object in which the properties of ATTENUATION of X-RADIATION are imaged

2.101.9
TOMOGRAPHIC SECTION THICKNESS
FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE taken at the centre of the cross-sectional volume over which TRANSMISSION data of X-RADIATION are collected

2.101.10
NOMINAL TOMOGRAPHIC SECTION THICKNESS
in CT SCANNERS the TOMOGRAPHIC SECTION THICKNESS which is selected and indicated on the CONTROL PANEL

2.202 Qualifying conditions for defined terms

This subclause of the General Standard does not apply.

6 Identification, marking and documents

This clause of the General Standard applies, except as follows:

6.8 ACCOMPANYING DOCUMENTS

Additional subclause:

6.8.101 Site test report

When means for emergency switching of the SUPPLY MAINS are to be incorporated on site by the USER, the requirements and site test procedures shall be specified in the ACCOMPANYING DOCUMENTS. The test results should be incorporated in the site test report.

SECTION 2: ENVIRONMENTAL CONDITIONS

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

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

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:

Additional subclauses:

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:

Additional subclause:

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 29.101. 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:

Replacement:

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 Collateral Standard IEC 60601-1-3 applies, except as follows:

Additional subclauses:

29.101 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 of all SUPPLY MAINS 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.

29.102 Dose statements and test equipment

29.102.1 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 29.102.2 placed on the PATIENT SUPPORT without additional attenuating material present. This dosimetry PHANTOM shall be centred in the scanfield 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 using the PHANTOM specified in 29.102.2:

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

   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 ($CTDI_{100}$ peripheral value).

   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.

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 subclause 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 midrange 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 midrange 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.

29.102.2 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.

29.103 Dose information

29.103.1 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 midrange 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 29.103.2.

29.103.2 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 29.103.1.

29.103.3 Weighted $CTDI_{100}$

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

$$1/3\ CTDI_{100}\ (\text{centre}) + 2/3\ CTDI_{100}\ (\text{peripheral});$$

see 29.102.1 a) items 1) and 2).

This $CTDI_W$ value shall be displayed on the OPERATOR'S console reflecting the type of examination selected, head or body, and the CT CONDITIONS OF OPERATION. If the NOMINAL TOMOGRAPHIC SECTION THICKNESS is not equal to the table increment per rotation, a corrected $CTDI_W$ value shall be displayed describing the average dose over the total volume scanned for the selected CONDITIONS OF OPERATION.

This is required in the following instances:

– multi-slice detection arrays,

– when the NOMINAL TOMOGRAPHIC SECTION THICKNESS is not equal to the table increment per rotation, or

– when the NOMINAL TOMOGRAPHIC SECTION THICKNESS is not equal to the table increment between two consecutive scans.

This list is not exclusive.

29.103.4 Geometrical efficiency in *z*-direction

The geometric efficiency in *z*-direction is the full width at half maximum of the SENSITIVITY PROFILE expressed as percentage of the full width at half maximum of the DOSE PROFILE. If there is more than one linear array of detectors, the sum of the SENSITIVITY PROFILES of each array shall be used. For those slices with an efficiency of less than 70 %, the actual geometrical efficiency in *z*-direction shall be displayed on the OPERATOR'S console.

29.104 FOCAL SPOT TO SKIN DISTANCE

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

29.105 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 backup 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 either by the OPERATOR or system failure, 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.

29.106 Control and indication of operable states

29.106.1 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 scan initiation is possible.

29.106.2 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, and audible indication shall be provided on the control panel. If the duration of LOADING is less than 0,5 s, the indication of LOADING shall be actuated for 0,5 s. 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.

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 – Subclauses 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 TUBE ASSEMBLIES and X-RAY SOURCE ASSEMBLIES and of first HALF-VALUE LAYER for TOTAL FILTRATION 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.

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 so 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 midrange 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).

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.

Additional subclause:

29.202.103 Indication and position of the TOMOGRAPHIC SECTION OR REFERENCE PLANE

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 or REFERENCE PLANE. 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, and the coincidence of the centre of the light field and the centre of the TOMOGRAPHIC PLANE shall be within 2 mm. If more than one tomographic section is acquired at a time, the ACCOMPANYING DOCUMENTS shall describe the position of the lightfield in reference to the tomographic section.

c) For motions of the PATIENT SUPPORT beginning at a typical starting position, and 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.

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

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

Replacement:

The ACCOMPANYING DOCUMENTS for all X-RAY TUBE ASSEMBLIES and X-RAY TUBE subassemblies 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.

29.206 ATTENUATION of the X-RAY BEAM

This subclause of the Collateral Standard IEC 60601-1-3 does not apply.

29.208 Protection against STRAY RADIATION

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

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 32 cm and a length of 14 cm to 20 cm 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 20 cm.

Additional subclause:

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.

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.

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 recorded examination data

a) When a RADIOGRAM of the preview image is provided (as described in 29.202.101 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.

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

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

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

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

Annex AA
(normative)

Terminology – Index of defined terms