IEC 60601-2-44

Edition 3.0 2012-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

AMENDMENT 1
AMENDEMENT 1

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

Appareils électromédicaux –
Partie 2-44: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de tomodensitométrie

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FOREWORD

This amendment has been prepared by subcommittee SC 62B: Diagnostic imaging equipment, of IEC Technical Committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62B/879/FDIS	62B/890/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

NOTE The attention of National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

Introduction to Amendment 1

The main topic addressed in this amendment is an extended concept of CTDI to accommodate CT SCANNERS with very large z-coverage. The other principal subject areas include:

1) a dose-check feature associated with a pre-scanning alert if expected values of dose indices exceed user-configurable DOSE NOTIFICATION VALUES or DOSE ALERT VALUES and
2) requirements covering the use of CT data in radiotherapy treatment planning (RTP).

The CT dose metric in use has been based on the $CTDI_{100}$, i.e. measurement of dose in PHANTOMs and limited integration of scattered radiation, and it is used in many countries' legislation to define "dose reference values" (also called "diagnostic reference levels") for CT examinations. Many people use these indices, $CTDI_{vol}$ and DLP, to derive estimates for effective dose via conversion factors. $CTDI_{100}$ is also part of CT acceptance and constancy testing. The introduction of a new dose index would change all CT SCANNERS' CTDI values. Therefore the intention is to stay with the $CTDI_{100}$, i.e. the integration of primary radiation and scatter over 100 mm, but adapt the way of measuring and reporting the dose index to incorporate large collimations and to rate all collimations the same way, i.e. to reflect approximately the same percentage of $CTDI_{\infty}$ for all collimations.

As defined in the amendment, $CTDI_{100}$ is to be measured only for collimations up to 40 mm with the current equipment, i.e. the PMMA PHANTOMs and a 100-mm chamber, or other suitable methods that use a RADIATION DETECTOR. For these collimations there is no significant change of the ratio $CTDI_{100}$ / $CTDI_{\infty}$ according to published data. For larger collimations at the same CT CONDITIONS OF OPERATION, the z-efficiency may be different and must be evaluated in the dose measurement. This can be accomplished by the measurement of dose 'free air'. Based on these considerations $CTDI_{100}$ and the $CTDI_{free\ air}$ have been refined. Both types of measurement are combined now to determine the CTDI values for larger collimations and they are explained in detail in informative Annexes CC and DD.

Some additional requirements and refinements related to dose have been added: $CTDI_{vol}$ and DLP are defined for a new type of scan mode ('shuttle mode'). In body CT EXAMINATION it is clarified that the $CTDI_{vol}$ and DLP always be reported for the 32-cm diameter PHANTOM. In the amendment it is now required that CT SCANNERS support user-configurable DOSE NOTIFICATION VALUES and DOSE ALERT VALUES.

A new subject area in this Amendment 1 covers requirements for CT SCANNERS providing images for radiotherapy treatment planning. With this amendment begins the implementation of this important CT application into the CT safety standard with a set of requirements that is considered to be safety relevant. It mainly covers scanner hardware adjustments, accuracy of CT image data, and the conversion of HU to electron and mass density.

201.1.1 Scope

Add the following new sentence:

The scope of this International Standard excludes RADIOTHERAPY SIMULATORS and systems where the image is created by a source other than an X-RAY TUBE.

201.1.3 Collateral standards

Replace the existing text of this subclause with the following:

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10[1], IEC 60601-1-11[2] and IEC 60601-1-12[3] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

For collateral standards published after this particular standard, MANUFACTURERS need to determine the applicability in accordance with the RISK MANAGEMENT PROCESS.

201.2 Normative references

Add, under "Replacement", the following new reference:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Add, under "Addition", the following new reference:

IEC 60336 *Medical electric equipment – X-Ray Tube assemblies for medical diagnosis – Characteristics of focal spots*

201.3 Terms and definitions

201.3.202
CT CONDITIONS OF OPERATION

Add a note 3 to this definition:

NOTE 3 CT CONDITIONS OF OPERATION include parameters that are derived by the system from the user-selectable parameters.

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[1] IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

[2] IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

[3] IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended to be used in the emergency medical services environment*

201.3.203
COMPUTED TOMOGRAPHY DOSE INDEX 100
***CTDI*$_{100}$**

Replace the existing text of the definition by the following:

integral of the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE divided by N x T according to the following:

for $N \times T$ less than or equal to 40 mm

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

for $N \times T$ greater than 40 mm (all CT CONDITIONS OF OPERATION except collimation are kept the same for these measurements)

$$CTDI_{100} = \int_{-50\,mm}^{+50\,mm} \frac{D_{Ref}(z)}{(N \times T)_{Ref}}\, dz \times \frac{CTDI_{free\ air,\, N \times T}}{CTDI_{free\ air,\, Ref}}$$

where

$D(z)$	is the DOSE PROFILE representative of a single axial scan along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 203.108);
$(N \times T)_{Ref}$	is a specific $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm;
$D_{Ref}(z)$	is the DOSE PROFILE representative of a single axial scan along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 203.108) for $(N \times T)_{Ref}$;
$CTDI_{free\ air,\ N \times T}$	is the $CTDI_{free\ air}$ (201.3.215) for a specific value of $N \times T$;
$CTDI_{free\ air,\ Ref}$	is the $CTDI_{free\ air}$ (201.3.215) for $(N \times T)_{Ref}$;
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 dose is reported as ABSORBED DOSE to air, but for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA.

NOTE 2 This definition assumes that the DOSE PROFILE is centred on z = 0.

NOTE 3 A single axial scan is typically a 360° rotation of the X-ray source.

NOTE 4 When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with a "z-flying FOCAL SPOT", the denominator of the integral needs to be replaced by the total nominal width along z of overlapping tomographic sections. For example, if the percentage of overlap is 50%, then the denominator would be replaced by 0,5 × N × T.

NOTE 5 Typically the z-axis is the axis of rotation.

NOTE 6 The $CTDI_{100}$ is designed to include most of the scattered radiation.

NOTE 7 See Annex CC for explanation.

201.3.204
CT PITCH FACTOR

*Replace, in Note 3, the text "*or $N \times T$ are*" by the word "*is*".*

201.3.212
VOLUME $CTDI_w$
$CTDI_{vol}$

a) for axial scanning

Replace Notes 1 and 2 by the following:

NOTE 1 For the selected CT CONDITIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_w$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of integration along the z-axis. For axial scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area × Δd.

NOTE 2 For axial scanning with a total table travel much less than $N \times T$, $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area ×Δd.

b) for helical scanning

In Note 1 replace the text "or $N \times T$ are" *by the text* "is".

Replace Notes 2 and 3 by the following:

NOTE 2 For the selected CT CONDITIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_w$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of integration along the *z*-axis. For helical scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the centre of a 100 mm scan length.

NOTE 3 For helical scanning, when the product of a small number of rotations times the table travel per rotation is much less than $N \times T$, $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the centre of a 100-mm scan length.

Add the following new item:

d) for axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)

$$CTDI_{vol} = n\,\frac{N \times T}{(N \times T) + R}\,CTDI_w$$

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;

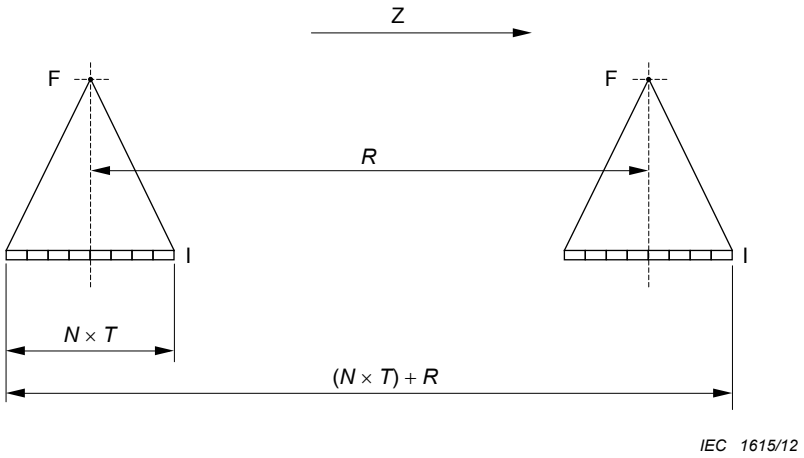
n is equal to the total number of rotations for the entire scan series;

R is the distance between the two positions;

$CTDI_W$ is the WEIGHTED $CTDI_{100}$.

NOTE 1 Seen Figure 201.102.

NOTE 2 $CTDI_w$ is evaluated as the time weighed $CTDI_w$ reflecting the varying CT CONDITIONS OF OPERATION.



F FOCAL SPOT

I ISOCENTRE

Z z-direction

Figure 201.102 – Illustration of *N* × *T*,*R* and (*N* × *T*) + *R*

201.3.214
DOSE-LENGTH PRODUCT
DLP

b) For helical scanning

Replace the existing text:

L is the table travel during the entire LOADING.

by the following new text:

L is the table travel during the entire LOADING, adjusted for dynamic collimation modes if applicable.

Add the following new note:

NOTE 3 A way for obtaining *L* could be to use the FWHM along a line perpendicular to the TOMOGRAPHIC PLANE at isocenter of the free-in-air DOSE PROFILE for the entire scan. In the absence of dynamic collimation this is approximately equivalent to table travel during the entire LOADING.

Add the following new item:

d) for axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)

$$DLP = CTDI_{vol} \times ((N \times T) + R)$$

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;

R is the distance between the two positions.

201.3.215
COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR
***CTDI*$_{\text{FREE AIR}}$**

Replace the existing symbol by the following:

***CTDI*$_{\text{free air}}$**

Replace the existing text of the definition by the following:

integral of the DOSE PROFILE representative of a single axial scan along a line through the ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following

$$CTDI_{\text{free air}} = \int_{-L/2}^{+L/2} \frac{D(z)}{N \times T} dz$$

where

$D(z)$ is the DOSE PROFILE representative of a single axial scan along a line z through ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated free-in-air in the absence of a PHANTOM and the PATIENT SUPPORT;

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;

L is at least ($N \times T$) +40 mm, but not less than 100 mm.

NOTE 1 This definition assumes that the DOSE PROFILE is centred on $z = 0$.

NOTE 2 When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with a "z-flying FOCAL SPOT", the denominator of the integral needs to be replaced by the total nominal width along z of overlapping tomographic sections. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by 0,5 × N × T.

NOTE 3 Typically a RADIATION DETECTOR of length L or longer is used. Annex DD provides an example for alternate measurements.

Add the following new terms and definitions:

201.3.216
PROTOCOL ELEMENT
set of the particular CT CONDITIONS OF OPERATION necessary to perform a scan

NOTE 1 The following modes are examples of different types of scan: helical, axial, axial series, scanning without movement of the patient support and shuttle mode.

NOTE 2 To maintain consistency with their respective user interfaces and documentation, various CT SCANNERS might use terminology different from "PROTOCOL ELEMENT", e.g., "scan", "scan group", "scan series", etc., which actually means "PROTOCOL ELEMENT"

NOTE 3 A PROTOCOL ELEMENT is typically associated with a defined clinical task, clinical context, anatomical region, and/or age or size group. It corresponds to one sequence of scanning in a CT EXAMINATION.

201.3.217
CT EXAMINATION
group of PROTOCOL ELEMENTS used for the entire COMPUTED TOMOGRAPHY PROCEDURE for a particular PATIENT

201.3.218
DOSE NOTIFICATION VALUE
value of $CTDI_{vol}$, $CTDI_{vol}$ per second, or DLP used to trigger a notification on the control panel

NOTE A DOSE NOTIFICATION VALUE could represent a level of concern associated with a dose index value that would exceed a value normally expected for the PROTOCOL ELEMENT (e.g. a diagnostic reference level or similar value determined by the RESPONSIBLE ORGANIZATION).

201.3.219
DOSE ALERT VALUE
value of $CTDI_{vol}$ or *DLP* used to trigger an alert on the control panel

NOTE A DOSE ALERT VALUE could represent a level of concern (e.g. avoidance of deterministic effects) higher than that of a DOSE NOTIFICATION VALUE, and it would therefore warrant more stringent review and consideration before proceeding."

201.4 General requirements

201.4.3 ESSENTIAL PERFORMANCE

Replace the existing text of this subclause with the following:

Addition:

For CT SCANNERS for which the INTENDED USE includes COMPUTED TOMOGRAPHY as the principal means of guidance in invasive procedures (e.g., involving the introduction of a device, such as a needle or a catheter into the body of the PATIENT), any ESSENTIAL PERFORMANCE aspects related to such use shall be identified in the ACCOMPANYING DOCUMENTS and in the RISK MANAGEMENT FILE.

NOTE An example of what would not be considered ESSENTIAL PERFORMANCE is the extraction of needles where images are not required for guidance.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.7.9.101 Reference to ACCOMPANYING DOCUMENTS

Replace the following line:

– LIGHT FIELD	203.115

by the following new line:

– Light marker	203.115 c)

Add the following new lines:

– ESSENTIAL PERFORMANCE	201.4.3
– Alignment of the top of the PATIENT SUPPORT	201.101.2
– Top of the PATIENT SUPPORT	201.101.3
– Table sag (stiffness of the PATIENT SUPPORT)	201.101.4
– Integral light markers for PATIENT marking	201.101.5
– Typical scan mode to provide images for RTP	201.101.6
– HU-value conversion	201.101.7
– Geometric accuracy of image data	201.101.8
– Information in the ACCOMPANYING DOCUMENTS	203.10.2
– Display and recording of $CTDI_{vol}$ and *DLP*	203.112

201.8.8.3 Dielectric strength

Replace the existing third paragraph with the following:

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 or X-RAY TUBE ASSEMBLY (whichever is lower).

NOTE 101 For the NOMINAL X-RAY TUBE VOLTAGE of the HIGH-VOLTAGE GENERATOR, see also subclause 201.8.4.101, Limitation of high voltage to the NOMINAL X-RAY TUBE VOLTAGE.

201.9.2.4.101.3 Linear movements of the PATIENT SUPPORT and gantry

In the last sentence of the first paragraph replace "25 mm after actuation" *with* "50 mm after actuation"*.*

Add the following two new paragraphs after the existing first paragraph:

If a scan mode is selected in which the PATIENT SUPPORT cannot stop within 25 mm after actuation of the emergency stop, before the scan is initiated the CT SCANNER shall display an alert on the CONTROL PANEL regarding this situation and instruct the OPERATOR to ensure the PATIENT area of travel is free from obstruction.

The ACCOMPANYING DOCUMENTS shall identify the scan modes that cannot meet the 25 mm emergency stop distance.

Replace the existing compliance statement by:

Compliance is checked by functional test and inspection of the ACCOMPANYING DOCUMENTS.

201.12.1.102 Accuracy of recorded CT EXAMINATION data

Replace existing item a)by the following:

a) When a RADIOGRAM for preview (as described in 203.115 of this particular standard) is provided, the position of the TOMOGRAPHIC SECTIONS shall be clearly indicated on the RADIOGRAM.

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

Add the following additional clauses:

201.101 Requirements for CT SCANNERS providing images for RADIOTHERAPY TREATMENT PLANNING (RTP)

201.101.1 General

Clause 201.101 applies only to CT SCANNERS whose INTENDED USE includes providing image data for RADIOTHERAPY TREATMENT PLANNING (RTP).

Requirements related to the CT SCANNER (gantry, PATIENT SUPPORT, light markers) and conversion of Hounsfield Units to electron and mass density are addressed.

201.101.2 Alignment of the top of the PATIENT SUPPORT

201.101.2.1 General

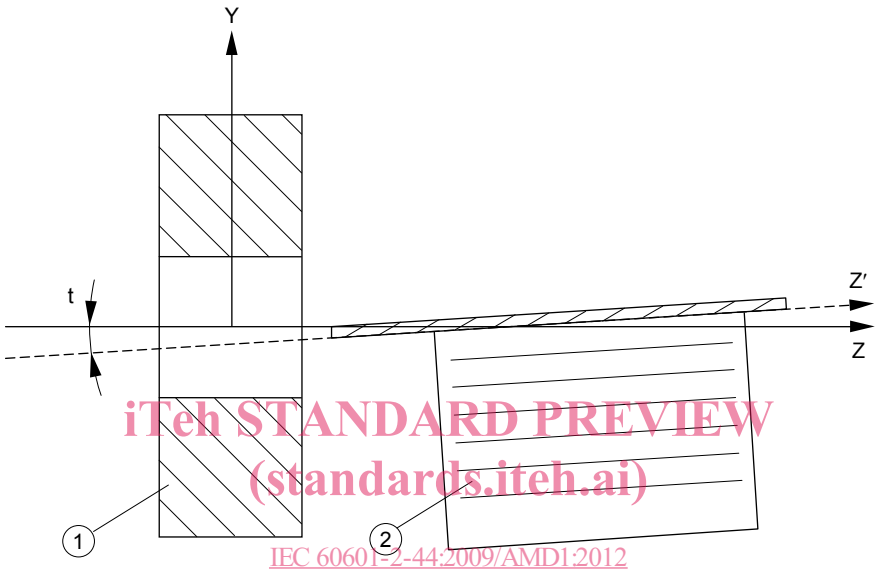
The ACCOMPANYING DOCUMENTS shall describe the procedures for aligning the top of the PATIENT SUPPORT with respect to the TOMOGRAPHIC PLANE such that the long axis of the top of the PATIENT SUPPORT is aligned vertically and horizontally over the maximum scan range along the z direction.

Compliance of the alignment requirements in subclauses 201.101.2.2 and 201.101.2.3 is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.101.2.2 Alignment of the PATIENT SUPPORT in the vertical plane (tilt)

The alignment procedure shall require the accuracy of the alignment to be ±0,5° or less with respect to the horizontal plane (Figure 201.103).

The alignment procedure shall require this measurement to be taken on the retracted top of the PATIENT SUPPORT, without load, after installation.



Z Z-axis

Z' Axis of the top of the PATIENT SUPPORT

t Tilt angle

1 Gantry

2 PATIENT SUPPORT

Figure 201.103 – Vertical alignment of the PATIENT SUPPORT

201.101.2.3 Alignment of the PATIENT SUPPORT in the horizontal plane

a) The alignment procedure shall require the axis of the horizontal movement of the top of the PATIENT SUPPORT to be perpendicular to the x-axis of the TOMOGRAPHIC PLANE within ± 1°.

b) The alignment procedure shall require the centerline of the top of the PATIENT SUPPORT to be marked at the front end (M1) and at a distance of 1 m from the front end (M2). The difference between the centerline and the z-axis indicated by the sagittal light marker shall be measured at the position of the scan plane for both M1 and M2. Neither d1 nor d2 shall exceed 2 mm (see Figure 201.104). If the sagittal light marker does not extend to the scan plane, the measurement shall be taken at the external light marker position.

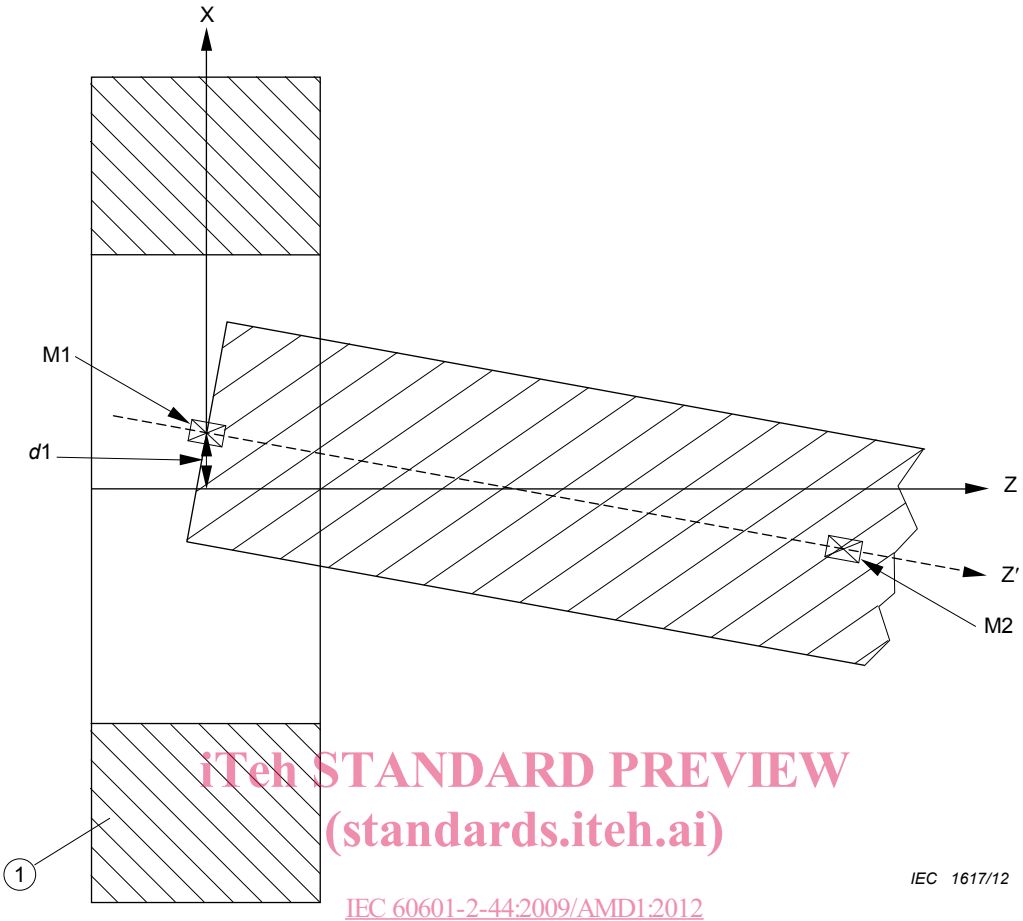


Figure 201.104a

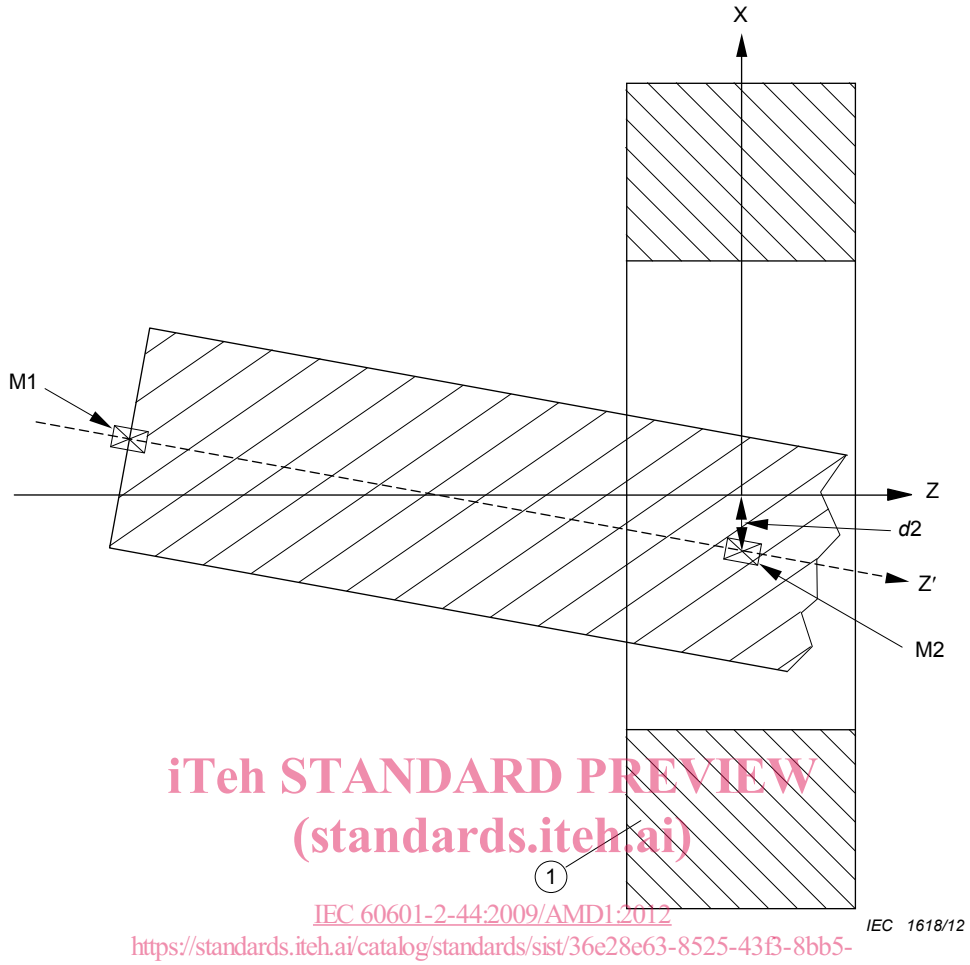


Figure 201.104b

Z Z-axis

Z' Axis of the top of the PATIENT SUPPORT

1 Gantry

M1, M2 Markings on the top of the PATIENT SUPPORT

*d*1, *d*2 distance of Markings from Z-axis

Figure 201.104 – Z-axis alignment of the PATIENT SUPPORT in the horizontal plane

201.101.3 Top of the PATIENT SUPPORT

The surface of the PATIENT SUPPORT shall be flat or an ACCESSORY to make it flat shall be specified in the ACCOMPANYING DOCUMENTS and shall be made available.

The PATIENT SUPPORT should allow use of the positioning aids of the therapy system.

201.101.4 Table sag (stiffness of the PATIENT SUPPORT)

Table sag shall be specified for ranges of 40 cm (typical scan length plus shift to reach the scan plane).

NOTE Corrections for table sag might be needed in the process of RTP.

The sag of the PATIENT SUPPORT in the scan plane shall be evaluated according to the following test specification: