

INTERNATIONAL STANDARD

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First edition
1998-09

Medical electrical equipment –
Part 2-45:
Particular requirements for the safety
of mammographic X-ray equipment
and mammographic stereotactic devices



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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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices

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 60601-2-45 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/343/FDIS	62B/353/RVD

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

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 roman type;

- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS STANDARD, IN IEC 60788 OR IN OTHER IEC STANDARDS REFERENCED IN ANNEX AA: SMALL CAPITALS.

NOTE – Attention is drawn to the existence of legislation in some countries concerning RADIATION safety which may not align with the provisions of this standard.

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

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Withdrawn

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices

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 contains requirements for the safety of X-RAY EQUIPMENT designed for mammography and MAMMOGRAPHIC STEREOTACTIC DEVICES.

1.2 Object

Replacement:

The object of this standard is to formulate appropriate design and manufacturing requirements for the safety of mammographic X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES, reflecting the particular characteristics and circumstances of use of such 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 1 (1991) and 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 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 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*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

2.101 Definitions

In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions either in the General Standard, in this standard, in IEC 60788 or in other IEC standards referenced in annex AA.

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.

For the purpose of this standard, the following additional definitions apply.

2.101.1

MAMMOGRAPHIC STEREOTACTIC DEVICE

device for three-dimensional localization of a point within the breast, and for mechanically guided placement of a needle or position marker for such purposes as fine-needle aspiration, core biopsy and pre-surgical localization. The localization is based on radiographic images of an immobilized breast acquired at different known angles. Such a device may be a dedicated system or an ACCESSORY for mammographic X-RAY EQUIPMENT

2.101.2

CORE BIOPSY GUN

automatic needle device for performing core biopsy

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

Addition:

NOTE – For the purpose of this clause, EQUIPMENT or EQUIPMENT parts includes all items that are within the scope of this standard; see 1.1.

aa) Marking of compliance

If compliance with this standard is to be marked on an item, such marking shall be made on the outside of the item in combination with the MODEL OR TYPE REFERENCE as follows:

.... ^{*)} IEC 60601-2-45:1998 ^{**)}.

^{*)} Description of item and MODEL OR TYPE REFERENCE

^{**)} Year of publication of this standard

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall include a declaration of the dimensions of all available X-RAY FIELDS.

The ACCOMPANYING DOCUMENTS of any MAMMOGRAPHIC STEREOTACTIC DEVICE designed as an ACCESSORY for mammographic X-RAY EQUIPMENT shall contain:

- at least one MODEL OR TYPE REFERENCE to mammographic X-RAY EQUIPMENT with which it is designed to operate;
- a reference to the relevant standards with which the MAMMOGRAPHIC STEREOTACTIC DEVICE complies.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

- The INSTRUCTIONS FOR USE shall contain instructions for the inspection and safe use of all compression plates used with the X-RAY EQUIPMENT.
- The INSTRUCTIONS FOR USE of MAMMOGRAPHIC STEREOTACTIC DEVICES shall contain:
 - instructions for the safe handling and use of needles and CORE BIOPSY GUNS;
 - the designation of the types of needles and CORE BIOPSY GUNS with which they are designed to be used and shall contain a warning against the use of any other types.

Addition:

aa) CONTROLLED AREA

The INSTRUCTIONS FOR USE shall draw the attention of the USER to the need to restrict access to the EQUIPMENT in accordance with local regulations for RADIOLOGICAL PROTECTION.

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:

21 Mechanical strength

This clause of the General Standard applies except as follows:

Addition:

21.101 Application of maximum compression force

21.101.1 Motion of ANTI-SCATTER GRID

For mammographic X-RAY EQUIPMENT with a moving ANTI-SCATTER GRID, the application of the maximum force attainable for the COMPRESSION DEVICE shall not impede the motion of the ANTI-SCATTER GRID.

Compliance is determined by the following test:

a) Test equipment

The following test equipment is required:

- *appropriately sized objects, one for each image receptor format, leading to sufficiently realistic force distributions when under compression. The objects shall be sand filled bags or soft rubber blocks. Their thickness shall be in the range from 20 mm to 50 mm. For the smallest image receptor format, the object shall be 100 mm to 120 mm long and wide, and it shall be 120 mm to 150 mm long and wide for larger formats;*
- *an aluminium plate of 2 mm thickness and of dimensions sufficient to intercept the whole X-RAY BEAM when mounted as described below;*
- *if the X-RAY EQUIPMENT uses RADIOGRAPHIC FILMS:*
 - *a densitometer, covering the optical density range from 0 to 3,5;*
 - *RADIOGRAPHIC CASSETTES with INTENSIFYING SCREENS and RADIOGRAPHIC FILMS for each image format.*

b) *Test procedure*

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast and set the X-RAY EQUIPMENT in a condition that is provided for grid mammography. Mount a compression plate that is designed for the maximum attainable compression force and for the image receptor format used. Fix the aluminium plate between the X-RAY SOURCE ASSEMBLY and the compression plate so that it will completely cover the X-RAY BEAM. Place the object on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is provided to be adjacent to the PATIENT's chest wall. If the object is a sand filled bag, shape it by hand to maximize the surface areas that will be in contact with the PATIENT SUPPORT and the compression plate. Actuate the breast COMPRESSION DEVICE to the maximum attainable compression force. For X-RAY EQUIPMENT using RADIOGRAPHIC FILMS, select an X-RAY TUBE VOLTAGE of 25 kV to 30 kV and a CURRENT TIME PRODUCT that will lead to an optical density of 1,0 to 2,0 in the darkest part of the RADIOGRAPHIC FILM, which will be outside the image of the object under compression. Irradiate and process the RADIOGRAPHIC FILM. For X-RAY EQUIPMENT using a non-film image receptor, select an X-RAY TUBE VOLTAGE and CURRENT TIME PRODUCT appropriate for the image receptor; irradiate the image receptor and display the image.

Evaluate the RADIOGRAM. In case of impeded grid motion owing to the high compression force, grid lines or some other image of the ANTI-SCATTER GRID structure will be visible in the area outside the image of the object under compression.

If the ANTI-SCATTER GRID structure is visible, repeat the test but without applying a compression force, in order to verify whether the compression force is the cause.

Repeat the test procedure for all image receptor formats.

c) *Interpretation of test results*

Compliance is achieved if the application of the compression force does not increase the visibility of the ANTI-SCATTER GRID structure.

21.101.2 Strength of compression plates

Compression plates and their mountings, unless marked to indicate the maximum compression force permitted to be applied, shall withstand the maximum compression force attainable when they are fitted to the EQUIPMENT. The marking may take the form of coding related to an explanation in the INSTRUCTIONS FOR USE.

Compliance is determined by the following test:

a) *Test equipment*

Test objects as described in 21.101.1 are required.

b) *Test procedure*

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Mount a compression plate that is designed for the maximum attainable compression force. Take the test object designed for the same image receptor format as the compression plate and place it on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is provided to be adjacent to the PATIENT's chest wall. If the object is a sand filled bag, shape it by hand to maximize the surface areas that will be in contact with the PATIENT SUPPORT and the compression plate.

Actuate the breast COMPRESSION DEVICE to the maximum attainable compression force. Then relax the force.

c) *Interpretation of test results*

Inspect the compression plate and associated parts for any signs of damage, especially for fissures. For compliance, the compression plates and associated parts are to be free from breakage, visible damage and permanent distortion.

22 Moving parts

This clause of the General Standard applies except as follows:

Addition:

22.101 Motion of X-RAY TUBE – image receptor assembly

The assembly shall be capable of being rigidly fixed in any position where it is designed to operate. Once fixed in any such position, the assembly shall not move without OPERATOR intervention. Movement of the assembly shall require continuous actuation by the OPERATOR. In the event of interruption of the SUPPLY MAINS, the assembly shall not put any resultant force exceeding 20 N on any part of the PATIENT.

When the breast COMPRESSION DEVICE is actuated to a force of more than 50 N, the speed or step size of any power-driven movements of the assembly as a whole shall be limited so that the OPERATOR will have adequate control for fine correction of its position without endangering the PATIENT. Motions needed for stereotactic imaging which do not include an intended movement of the breast are excluded from this requirement.

22.102 COMPRESSION DEVICE

22.102.1 General

All mammographic X-RAY EQUIPMENT shall be fitted with a breast COMPRESSION DEVICE.

22.102.2 Control of compression movements

All switches controlling movement for the application of compression shall be of the type requiring continuous actuation while movement takes place. The X-RAY EQUIPMENT shall provide means for hands-free initiation of compression. It shall include means for fine adjustment of motion during the application of the compression force and for decompression. All functions shall be accessible from both sides of the position of the PATIENT.

Means shall be provided for the OPERATOR to prevent automatic decompression.

In the event of interruption of SUPPLY MAINS, the compression shall be maintained. However, means shall be provided for manually achieving complete decompression.

22.102.3 Range of movement

In all conditions of NORMAL USE, the available range of movement of the COMPRESSION DEVICE shall allow all those parts of the compression plate that are designed to be in contact with the breast to be brought within 10 mm of the surface of the PATIENT SUPPORT.

NOTE – This requirement is intended to ensure that adequate compression of small or thin breasts is not prevented by limitation of the available movement of the compression plate. The extent of compression applied to any particular PATIENT is controlled by the OPERATOR and may be limited by restriction of the available operating force; see 22.102.5.

22.102.4 Design of compression plates

Compression plates shall be transparent so that the skin of the PATIENT remains visible when in contact with them. Unless other means for indication are provided, the X-RAY EQUIPMENT shall include at least one compression plate for each image receptor format used in an AUTOMATIC EXPOSURE CONTROL mode marked to indicate the range of sensor positions available in NORMAL USE.

22.102.5 Compression force

COMPRESSION DEVICES shall satisfy the following requirements in respect of the application and indication of the compression force in all orientations specified for NORMAL USE:

- no COMPRESSION DEVICE shall be able to apply a force exceeding 300 N;
- for power-driven compression, the COMPRESSION DEVICE shall be able to apply a force of at least 150 N, and it shall be unable to apply a force exceeding 200 N;
- for power-driven compression, the available operating force shall be adjustable down to 70 N or less;
- if the value of the applied force is displayed, the indication shall be given in units of force and shall be accurate to ± 20 N.

Compliance is checked by measurement.

a) Test equipment

The following test equipment is required:

- a force balance;
- a soft rubber block, 20 mm to 50 mm thick, and 100 mm to 120 mm long and wide.

b) Test procedure

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Place the force balance on the PATIENT SUPPORT and fix it so that it will not fall down in any orientation. Place the soft rubber block on the sensitive area of the force balance. Operate the COMPRESSION DEVICE, thus clamping the soft rubber block, and record the reading of the balance. Measure the highest achievable forces for all compression modes. If the force is displayed at the X-RAY EQUIPMENT then perform at least five additional measurements for lower compression forces, equally distributed over the range from zero compression to the maximum attainable compression force and record all displayed values in combination with the readings of the balance. Repeat the test procedure for at least three other orientations of the X-RAY TUBE – image receptor assembly in order to cover the whole range of angles possible with the X-RAY EQUIPMENT sufficiently.

Repeat this test procedure for all modes of power-driven compression after adjusting the available operating force down to its minimum.

c) Interpretation of measured data

Determine compliance by comparing MEASURED VALUES with required values and, if the compression force is displayed, with the above requirements of accuracy.

22.103 MAMMOGRAPHIC STEREOTACTIC DEVICE

22.103.1 Positioning of X-RAY SOURCE ASSEMBLY for stereotactic imaging

In stereotactic imaging, defined angular positions shall be provided for the X-RAY SOURCE ASSEMBLY. The X-RAY SOURCE ASSEMBLY shall be capable of being rigidly fixed in any of these positions. Once fixed in any such position, the X-RAY SOURCE ASSEMBLY shall require OPERATOR intervention to release.

22.103.2 Motion of APPLIED PARTS during imaging and biopsy or marker placing

Under constant compression force, there shall be no displacement between the PATIENT SUPPORT and the compression plate of more than $\pm 0,5$ mm and $\pm 0,5^\circ$ relative to each other, and their displacement relative to the PATIENT shall not exceed ± 2 mm and $\pm 2^\circ$. The movement of the needle holder or CORE BIOPSY GUN holder with a needle inserted in it shall require continuous actuation and control by the OPERATOR.

22.103.3 Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES

The accuracy of biopsy needle tip position in x, y, and z directions shall be within ± 1 mm in the specified stereotactic biopsy volume.

Compliance is checked by measurement.

a) Test equipment

A stereotactic TEST DEVICE of a design which allows testing for different biopsy needle directions is required for the test. It consists of a mounting plate which is perforated so that it can serve as a locator for the test needles. At least three steel needles of different lengths are to be fixed in the mounting plate, the outer parts perpendicular to its surface, and pointing in the same direction. An example of the arrangement is shown in figure 1.

The steel needles are test needles, their tips serve as test objects. They shall be placed in a pattern so that the specified stereotactic biopsy volume can be covered. It shall be possible to locate one of them within ± 5 mm of the centre of that volume, and two of the other test needle tips also inside the specified stereotactic biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed with the MAMMOGRAPHIC STEREOTACTIC DEVICE.

b) Test procedure

Measure the biopsy needle length and compare the result to the nominal biopsy needle length, or to the biopsy needle length value stored or programmed in the MAMMOGRAPHIC STEREOTACTIC DEVICE. The measured length shall agree with the nominal length to within $\pm 0,3$ mm. Place the TEST DEVICE on the PATIENT SUPPORT of the MAMMOGRAPHIC STEREOTACTIC DEVICE, so that one of the test needle tips is located to within ± 5 mm of the centre of the specified stereotactic biopsy volume, and two of the other test needle tips are also located inside the specified stereotactic biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed. An attenuating, homogeneous material, for example 2 mm Al, may be attached close to the X-RAY SOURCE ASSEMBLY.

Select a FOCAL SPOT with which the MAMMOGRAPHIC STEREOTACTIC DEVICE is specified to be used.

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Acquire a pair of stereo views. On each image select all projections of the test needle tips within the specified stereotactic biopsy volume and reconstruct their x, y, z positions. For each test needle, position the biopsy needle tip according to the position calculated by the MAMMOGRAPHIC STEREOTACTIC DEVICE. Measure and record the differences in x, y, z positions between each test needle tip and the biopsy needle tip. Repeat the procedure with the X-RAY TUBE ASSEMBLY – image receptor assembly rotated to the extremities of the range specified by the MANUFACTURER for clinical use of angular deviation in each direction and also to any intermediate deviations of 90 degrees or multiples thereof. If the MAMMOGRAPHIC STEREOTACTIC DEVICE is designed for more than one biopsy needle direction relative to the X-RAY TUBE ASSEMBLY – image receptor assembly, then repeat the procedure at six different directions within the range specified by the MANUFACTURER for clinical use, including at least two directions at extremities of the specified range.

c) Interpretation of measured data

Compare the differences in x, y, and z directions to the requirement above.

NOTE – As visibility of all needle tips on the RADIOGRAMS is essential for the test procedure, it is important to avoid any overexposure of RADIOGRAPHIC FILM. Depending on the type of X-RAY EQUIPMENT, the attenuating material addressed in the description of the test procedure might be helpful for reaching this aim.

24 Stability in NORMAL USE

This clause of the General Standard applies except as follows:

Addition:

24.101 Mammographic X-RAY EQUIPMENT shall not overbalance if subjected to a force of 25 % of its weight or 220 N, whichever is less.

The force is to be applied in the direction and location most likely to overbalance the mammographic X-RAY EQUIPMENT. Legs or wheels shall be blocked in the most unfavourable position. The force shall be applied at the highest point or at a point 150 cm above floor level, whichever is the lower.

Mammographic X-RAY EQUIPMENT shall fulfil these requirements in all working conditions of NORMAL USE.

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:

Addition:

NOTE – There are two clauses in section 4 (clause 21, clause 22) which contain requirements of mechanics, but which, in actual fact, also address protection against hazards from unwanted or excessive RADIATION.

29 X-RADIATION

This clause of IEC 60601-1-3 applies except as follows:

29.201.5 TOTAL FILTRATION in X-RAY EQUIPMENT

Replacement of the first paragraph:

In X-RAY EQUIPMENT, the TOTAL FILTRATION arising from material in the X-RAY BEAM incident to the PATIENT, excluding the material of any compression plate provided for use in mammography, shall be:

Addition:

29.201.9 Test for HALF-VALUE LAYER

For X-RAY EQUIPMENT specified exclusively for mammography, ensure that the compression plate is not in the X-RAY BEAM during the determination.

NOTE – The exclusion of the compression plate from the measurement is not in contradiction to 29.201.2 of IEC 60601-1-3 because mammographic X-RAY EQUIPMENT usually includes perforated compression plates for breast biopsy.

29.203.4 Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA

Replacement:

Means shall be provided to enable the X-RAY FIELD to be positioned to cover the region of interest and the SENSITIVE VOLUMES of the AUTOMATIC EXPOSURE CONTROL.

When the X-RAY FIELD is adjusted in NORMAL USE for full coverage of the IMAGE RECEPTION AREA, it shall correspond to the PATIENT SUPPORT and the IMAGE RECEPTION AREA within the following limits.

The X-RAY FIELD

- a) shall extend to the edge of the PATIENT SUPPORT that is designed to be adjacent to the chest wall of the PATIENT and shall not extend beyond this edge by more than 5 mm.
- b) shall not extend by more than 2 % of the perpendicular distance from the IMAGE RECEPTOR PLANE to the position of the FOCAL SPOT beyond all edges of the IMAGE RECEPTION AREA.

NOTE – The position of the tolerance zone in item b) above has been changed so as not to exclude the possibility of irradiating the entire film area of mammograms. This permits the USER to avoid transparent margins on the film, where this is considered to be justified in the interests of reading diagnostic information from the mammograms, especially in circumstances where the masking of films during viewing is impracticable.

See annex BB for rationale.

29.207 PRIMARY PROTECTIVE SHIELDING

Replacement:

29.207.1 Requirements

Mammographic X-RAY EQUIPMENT shall be provided with PRIMARY PROTECTIVE SHIELDING in accordance with the requirements below. These requirements shall be met for all combinations of X-RAY FIELDS and perpendicular distances from the IMAGE RECEPTOR PLANE to the position of the FOCAL SPOT in NORMAL USE.

The PRIMARY PROTECTIVE SHIELDING shall extend at least to the projection of the PATIENT SUPPORT at the edge designed to be adjacent to the PATIENT's chest wall and at the other edges shall extend beyond the X-RAY FIELD by at least 1 % of the perpendicular distance from the IMAGE RECEPTOR PLANE to the position of the FOCAL SPOT.

The maximum permitted AIR KERMA is 1 μ Gy per IRRADIATION.

The reference X-RAY TUBE VOLTAGE for compliance shall be the NOMINAL X-RAY TUBE VOLTAGE.

The reference LOADING FACTORS for compliance shall be those corresponding to the MAXIMUM ENERGY input in a single LOADING according to the RADIOGRAPHIC RATINGS.

If LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the ACCOMPANYING DOCUMENTS shall include instructions for obtaining appropriate LOADING FACTORS for test.

Compliance is checked by inspection, by examination of the design documentation and ACCOMPANYING DOCUMENTS, and by the test described in 29.207.2 of IEC 60601-1-3.

29.208 Protection against STRAY RADIATION

Addition:

29.208.101 PROTECTIVE BARRIER

Mammographic X-RAY EQUIPMENT for which a SIGNIFICANT ZONE OF OCCUPANCY is designated shall have a PROTECTIVE BARRIER which is designed to be placed between the SIGNIFICANT ZONE OF OCCUPANCY and the region of the PATIENT SUPPORT. The PROTECTIVE BARRIER shall not prevent the OPERATOR from observing the PATIENT during the acquisition of mammograms. It shall extend from not more than 15 cm above the floor to a height of not less than 185 cm, and its width shall not be smaller than 60 cm.

NOTE – The height of a SIGNIFICANT ZONE OF OCCUPANCY as specified in IEC 60601-1-3 does not necessarily imply that the PROTECTIVE BARRIER as specified in this standard has the same height.

With an emitting TARGET of molybdenum, an X-RAY TUBE VOLTAGE of 35 kV with a PERCENTAGE RIPPLE of not more than 4, and a TOTAL FILTRATION of 0,03 mm molybdenum, the ATTENUATION EQUIVALENT of this PROTECTIVE BARRIER shall not be smaller than 0,08 mm of lead.

The PROTECTIVE BARRIER shall be permanently marked with its ATTENUATION EQUIVALENT with reference to this standard.

NOTE – The particular requirements in 29.208.101 of IEC 60601-1-3 are added for practical reasons, mainly in order to provide a lower limit for the ATTENUATION EQUIVALENT of PROTECTIVE BARRIERS that is usually appropriate for mammographic X-RAY EQUIPMENT. However, their fulfilment does not necessarily imply fulfilment of the requirements of the General Standard, and of local regulations and requirements for the limits of EFFECTIVE DOSE applicable to the OPERATOR.

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.

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.

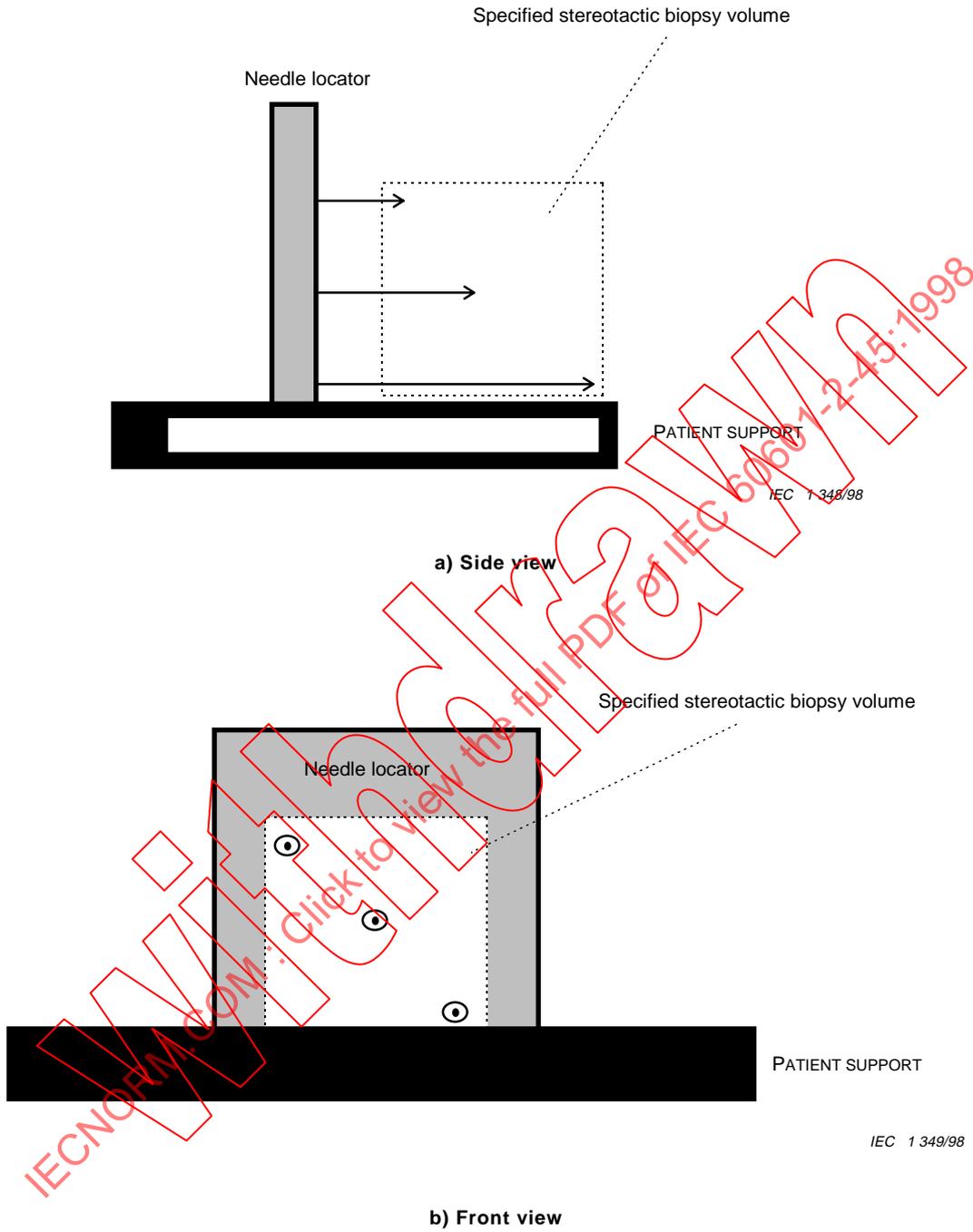


Figure 1 – Example of a TEST DEVICE for MAMMOGRAPHIC STEREOTACTIC DEVICES

Annex AA (normative)

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