INTERNATIONAL STANDARD

IEC 61331-3

First edition
1998-11

Protective devices against diagnostic medical X-radiation –

Part 3: Protective clothing and protective devices for gonads

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical –

Partie 3: Vêtements et dispositifs de protection radiologique des gonades

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* See web site address on title page.

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 3: Protective clothing and protective devices for gonads

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 61331-3 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/347/FDIS	62B/357/RVD

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

Annex A forms an integral part of this standard.

Annex B is for information only.

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

PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 3: Protective clothing and protective devices for gonads

1 Scope and object

1.1 Scope

This part of International Standard IEC 61331 applies to PROTECTIVE DEVICES such as PROTECTIVE CLOTHING for the protection of persons against X-RADIATION up to 150 kV, during RADIOLOGICAL examinations and interventional procedures.

NOTE – PROTECTIVE DEVICES are not intended by themselves to provide complete protection of persons, but are used to reduce the dose to persons where other methods of protection against X-RADIATION are insufficient or not applicable.

1.2 Object

This standard deals with:

– general requirements on the ACCOMPANYING DOCUMENTS, and on design and materials used;

– standard sizes, particular design features, minimum ATTENUATION properties of materials, marking and standardized forms of statements of compliance with this standard.

It covers PROTECTIVE CLOTHING mainly for the protection of the OPERATOR, such as:

– PROTECTIVE APRONS;

– PROTECTIVE GLOVES;

– PROTECTIVE MITTENS;

and PROTECTIVE DEVICES for gonads for the protection of the PATIENT, such as:

– PROTECTIVE GONAD APRONS;

– SCROTUM SHIELDS;

– OVARY SHIELDS;

– SHADOW SHIELDS.

The latter group of PROTECTIVE DEVICES is intended to be used during RADIOLOGICAL examinations to minimize the effects of IRRADIATION on the reproductive organs particularly with regard to genetic damage.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61331. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 61331 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61331-1:1994, *Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials*

3 Terminology

3.1 Degree of requirements

In this standard, certain terms which are not printed in SMALL CAPITALS have particular meanings, as follows:

– "shall" indicates a requirement that is mandatory for compliance;

– "should" indicates a strong recommendation that is not mandatory for compliance;

– "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;

– "specified" is used to indicate definitive information stated by the MANUFACTURER in ACCOMPANYING DOCUMENTS or in other documentation relating to the equipment under consideration, usually concerning its intended purpose, or the parameters or conditions associated with its use or with testing to determine compliance.

3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in IEC 60788, in this standard or in other IEC publications referenced in annex A.

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

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

3.3 Defined terms

For the purpose of this part of IEC 61331 the following additional definitions apply.

3.3.1
PROTECTIVE GONAD APRON

PROTECTIVE APRON worn by the PATIENT to protect the region of the gonads as an alternative to the use of a SCROTUM SHIELD or an OVARY SHIELD; see rm-64-05 of IEC 60788

3.3.2
SHADOW SHIELD

PROTECTIVE DEVICE to intercept the RADIATION BEAM in the areas of the gonads, to be used when a SCROTUM SHIELD and an OVARY SHIELD cannot be used

3.3.3
PROTECTIVE MITTEN

PROTECTIVE GLOVE with open palm and separated thumb used where full perception of touch is essential

4 General

4.1 ACCOMPANYING DOCUMENTS

PROTECTIVE DEVICES shall not be provided without ACCOMPANYING DOCUMENTS.

The ACCOMPANYING DOCUMENTS shall contain information on the following:

a) identity of the items of PROTECTIVE DEVICE(S) to which they apply, by reference to type or to individual items, as appropriate;

b) description of all markings on the items, with explanation of their meanings;

c) INSTRUCTIONS FOR USE, which shall contain:

d) recommendations for storage when not in use;

e) recommendations for methods and materials to be used for cleaning and disinfection;

f) recommended method and frequency of periodic inspection by the USER in order to verify the maintenance of ATTENUATION properties;

g) particulars of compliance with this standard.

Any information included in the ACCOMPANYING DOCUMENTS that is particularly intended to be read by the PATIENT, shall be repeated in a separate part containing all such information.

4.2 Language of the ACCOMPANYING DOCUMENTS

This standard contains no requirements concerning the language(s) in which the ACCOMPANYING DOCUMENTS provided are to be written.

Attention is drawn to the fact that when the ACCOMPANYING DOCUMENTS are written in a language other than that in which they were originally drafted and approved by the MANUFACTURER of the PROTECTIVE DEVICES, these documents shall be checked carefully by an expert who, wherever possible, should be authorized by the MANUFACTURER to act in that capacity.

The ACCOMPANYING DOCUMENTS shall state the language(s) in which they were originally drafted, approved or supplied by the MANUFACTURER and shall give a reference identifying at least one original version.

4.3 General requirement on marking

PROTECTIVE DEVICES shall be marked so that their correlation to the pertaining ACCOMPANYING DOCUMENTS is ensured.

4.4 Design

4.4.1 PROTECTIVE DEVICES for the protection of OPERATORS should be so designed that they can be put on and taken off without assistance.

4.4.2 PROTECTIVE DEVICES for the protection of the PATIENT shall be designed so that they can be easily applied, and they should be designed so that they can be properly placed and, where necessary, fixed by the PATIENTS themselves.

4.5 Materials

4.5.1 The materials effecting the ATTENUATION shall be homogeneously distributed and shall contain elements of high atomic number.

4.5.2 The ATTENUATION properties shall not vary under conditions of NORMAL USE.

4.5.3 All outer and inner accessible surfaces of PROTECTIVE DEVICES shall be suitable for cleaning and disinfection.

4.5.4 It shall not be possible to touch uncovered or uncoated surfaces of metallic lead or lead compounds.

5 PROTECTIVE APRONS

NOTE – PROTECTIVE APRONS are intended to be worn by persons who are present in the EXAMINATION ROOM during RADIOLOGICAL examinations with or without interventional procedures. They are intended primarily to protect the main part of the body of the OPERATOR. To protect the complete body, additional protective devices have to be used, for example thyroid shields, protective eye glasses or helmets.

For the purpose of this standard, four different categories of PROTECTIVE APRONS are defined:

– light PROTECTIVE APRONS;

– heavy PROTECTIVE APRONS;

– light closed PROTECTIVE APRONS;

– heavy closed PROTECTIVE APRONS.

NOTE – Light PROTECTIVE APRONS may be worn for example in the operating theatre and in the gypsum room, or if the SIGNIFICANT ZONE OF OCCUPANCY is protected against STRAY RADIATION by other PROTECTIVE DEVICES, for example fixed on the X-RAY EQUIPMENT.

5.1 Design

PROTECTIVE APRONS shall consist of one or more layers of protective material and shall be designed to cover the front part of the body from the throat down to at least the knees, the entire breastbone and the shoulders.

The width of the protective material on each shoulder shall be not less than 11 cm and these shoulder pieces shall extend over the back of the shoulders for at least 15 cm.

Unprotected stitch holes fixing parts together shall be allowed only on the back of a PROTECTIVE APRON.

NOTE – The X-RADIATION through stitch holes fixing the parts together may be neglected on the back because of the relative movements between the OPERATOR and X-RAY SOURCE.

Closed PROTECTIVE APRONS shall be designed to cover, additionally:

– the sides of the body from not more than 10 cm below the armpit to at least half-way down the thigh;

– the back down to the knees.

Closed PROTECTIVE APRONS should be designed to permit ventilation. For this purpose, overlapping fastenings at the sides, the openings of which point towards the back, or a fastening leaving uncovered a vertical slit in the middle of the back may be provided.

NOTE 1 PROTECTIVE APRONS may consist of two overlapping pieces, a vest and a skirt.

NOTE 2 PROTECTIVE APRONS may have provision for the attachment of additional material to increase the ATTENUATION EQUIVALENT in areas where sensitive organs may be endangered during particular examinations.

NOTE 3 Closed PROTECTIVE APRONS may have overlapping fastenings at the front.

5.2 Materials

The protective material as well as any fabric covering and binding shall be flexible.

a) The ATTENUATION EQUIVALENT of light PROTECTIVE APRONS shall be not less than 0,25 mm Pb over their entire area.

b) The ATTENUATION EQUIVALENT of heavy PROTECTIVE APRONS shall be not less than 0,35 mm Pb for the front section, and not less than 0,25 mm Pb for the remaining parts.

c) The ATTENUATION EQUIVALENT of light closed PROTECTIVE APRONS shall be not less than 0,25 mm Pb over their entire area.

d) The ATTENUATION EQUIVALENT of heavy closed PROTECTIVE APRONS shall be not less than 0,35 mm Pb for the front section, and not less than 0,25 mm Pb for the remaining parts.