SLOVENSKI STANDARD
SIST EN 61267:1995

01-maj-1995

Medical diagnostic X ray equipment Radiation conditions for use in the determination of characteristics (IEC 1267:1994)

Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics

Medizinische diagnostische Röntgeneinrichtungen - Bestrahlungsbedingungen zur Bestimmung von Kennmerkmalen

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Equipement de diagnostic médical à rayonnement X - Conditions de rayonnement pour utilisation dans la détermination des caractéristiques

SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ec8360-6969-42af-92dc-e3b0469e1358/sist-en-61267-1995

Ta slovenski standard je istoveten z: **EN 61267:1994**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 61267:1995 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

SIST EN 61267:1995

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ec8360-6969-42af-92dc-e3b0469e1358/sist-en-61267-1995

EUROPEAN STANDARD EN 61267

NORME EUROPEENNE

EUROPAISCHE NORM November 1994

ICS 11.040.50

Descriptors: Electromedical equipment, X-ray equipment, diagnostic, radiation, characteristics

ENGLISH VERSION

Medical Diagnostic X-Ray Equipment - Radiation conditions for use in the determination of characteristics
(IEC 1267:1994)

Equipement de diagnostic médical à rayonnement X - Conditions de rayonnement pour utilisation dans la détermination des caractéristiques
(CEI 1267:1994)

Medizinische diagnostische Röntgen-Einrichtungen Bestrahlungsbedingungen zur Bestimmung von Kennmerkmalen

(IEC 1267:1994)

iTeh STANDARD PREVIEW
(standards.iteh.ai)
https://standards.iteh.ai/catalog/standards/sist/61ec3580-6996-42af-8dc-e3b0469e1338/sist-en-61267-1995
SIST EN 61267:1995

This European Standard was approved by CENELEC on 1994-05-15. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

© 1994 Copyright reserved to CENELEC members

SIST EN 61267:1995

FOREWORD

The text of document 62B(CO)110, as prepared by Sub-Committee 62B: Diagnostic imaging equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in July 1993.

The reference document was approved by CENELEC as EN 61267 on 15 May 1994.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1995-09-01

- latest date of withdrawal of conflicting national standards (dow) 1995-09-01

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given only for information. In this standard, annexes A and ZA are normative and annexes B and C are informative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 1267:1994 was approved by CENELEC as a European Standard without any modification.

---

iTeh STANDARD PREVIEW
(standards.iteh.ai)
https://standards.iteh.ai/catalog/standards/sist/b1f8360-6969-42af-92dc-e30469e1358e/sist-en-61267-1995
SIST EN 61267:1995
SIST EN 61267:1995

SIST EN 61267:1995

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

NOTE : When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	Date	Title	EN/HD	Date
601-1 A1	1988 1991	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 A1 A11 A12	1990 1993 1993 1993
731 + A1	1982	Medical electrical equipment Dosimeters with ionization chambers as used in radiotherapy	HD 534 S1	1989
788	1984	Medical radiology - Terminology	HD 501 S1	1988
1223-1	1993	Evaluation and routine testing in medical imaging departments Part 1: General aspects	-	-

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ee8330-6969-42af-92dc-e3b0468e1358/sist-en-61267-1995

Other publication:

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

SIST EN 61267:1995

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ec8360-6969-42af-92dc-e3b0469e1358/sist-en-61267-1995

SIST EN 61267:1995

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
1267

Première édition
First edition
1994-09

Equipement de diagnostic médical à rayonnement X – Conditions de rayonnement pour utilisation dans la détermination des caractéristiques

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics

SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/01ce8560-6989-42af-92dc-e3b0469e1358/sist-en-61267-1995

© CEI 1994 Droits de reproduction réservés — Copyright – all rights reserved

Aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'éditeur.

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Bureau Central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève, Suisse

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE U

Pour prix, voir catalogue en vigueur
For price, see current catalogue

SIST EN 61267:1995

CONTENTS

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ec8360-6969-42af-92de-e3b0469e1358/sist-en-61267-1995

SIST EN 61267:1995

Clause Page

Tables

Figures

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ee836d-6969-42af-92dc-e3b0469e1358/sist-en-61267-1995

Annexes

SIST EN 61267:1995

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DIAGNOSTIC X-RAY EQUIPMENT –

RADIATION CONDITIONS FOR USE IN THE DETERMINATION OF CHARACTERISTICS

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 cooperation 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, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subject dealt with.

3) They have the form of recommendations for international use 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, the 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ec8360-6969-42af-92dc-e3b0469e1358/sist-en-61267-1995

International Standard IEC 1267 has been prepared by sub-committee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

It forms the first edition of IEC 1267.

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

DIS	Report of voting
62B(CO)110	62B(CO)122

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

Annex A forms an integral part of this standard.

Annexes B and C are for information only.

SIST EN 61267:1995

INTRODUCTION

To establish characteristics, aspects or properties of associated equipment or to have available radiation beams for physical and medical investigations, sets of well-defined radiation conditions can offer an important tool in many situations.

From a regulation and standardization point of view there is a need:

– to have available well-defined RADIATION CONDITIONS that can be used internationally to specify standards of operation of X-RAY EQUIPMENT;

– to provide a basis for the harmonization of existing national standards;

– to provide uniform sets of RADIATION CONDITIONS (a dictionary of RADIATION CONDITIONS) to describe and judge the performance of X-RAY EQUIPMENT for the benefit of MANUFACTURERS, USERS, PATIENTS and health protection authorities;

– to solve communication problems between MANUFACTURERS, USERS and regulatory authorities, stemming from a lack of internationally accepted definitions and test methods.

From an application point of view commonly accepted sets of RADIATION CONDITIONS would in general find use in:

iTeh STANDARD PREVIEW
(standards.iteh.ai)

- QUALITY CONTROL tests by MANUFACTURERS;
- installation and ACCEPTANCE TESTS;
- calibration of test instrumentation;
- type approval tests (where required);
- inspection and tests by regulatory authorities and testing institutes;

SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/61ec8360-6969-42af-92dc-e3b0469e1358/sist-en-61267-1995

- physical and medical studies in physical laboratories and medical facilities;
- determination of characteristics of ASSOCIATED EQUIPMENT.

Standard RADIATION CONDITIONS can benefit a number of potential users, such as:

- MANUFACTURERS of X-RAY EQUIPMENT;
- MANUFACTURERS of X-ray test instrumentation;
- research laboratories;
- testing institutes;
- USERS;
- government regulatory authorities;
- service organizations;
- standardization organizations.

Some provisions and statements in the body of this International Standard require additional information. Such information is presented in annex B called "Rationale". An asterisk in the left-hand margin of a clause or subclause indicates the presence of such additional information.

A comprehensive survey for the application of all standard RADIATION CONDITIONS in the medical field is given in annex C.

SIST EN 61267:1995

MEDICAL DIAGNOSTIC X-RAY EQUIPMENT –

RADIATION CONDITIONS FOR USE IN THE DETERMINATION OF CHARACTERISTICS

1 Scope and object

* 1.1 *Scope*

This International Standard applies to test procedures which, for the determination of characteristics of systems or components of medical diagnostic X-RAY EQUIPMENT, require well-defined RADIATION CONDITIONS.

Except for mammography, this standard does not apply to conditions where discontinuities in radiation absorption of elements are deliberately used to modify properties of the RADIATION BEAM (for example by rare earth filters).

Speed measurements of screen-film systems are not included in this standard. This topic will be covered by an ISO standard.

* 1.2 *Object*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This standard deals with methods for generating RADIATION BEAMS with RADIATION CONDITIONS which can be used under test conditions typically found in test laboratories or in manufacturing facilities for the determination of characteristics of medical diagnostic X-RAY EQUIPMENT.

SIST EN 61267:1995
https://standards.iteh.ai/catalog/standards/sist/...-61267-1995

Examples of such RADIATION CONDITIONS are those emerging from the X-RAY TUBE ASSEMBLY or RADIATION CONDITIONS that simulate those emerging from an EXIT SURFACE of the PATIENT.

The most complete specification of RADIATION CONDITIONS is given by the spectral distribution of the RADIATION BEAM. Since the characterization of typical X-RAY SPECTRA is such a difficult measurement problem, this standard expresses RADIATION CONDITIONS in terms of a modified HALF-VALUE LAYER technique or, where applicable, with water phantoms with regard to defined geometric conditions.

This standard describes both primary RADIATION CONDITIONS, which to a good approximation are free of SCATTERED RADIATION (RQR and RQA) and, for PATIENT simulation, RADIATION CONDITIONS containing SCATTERED RADIATION (RQN, RQB, RQN-M and RQB-M).

It is crucial to be aware that in the presence of SCATTERED RADIATION the characteristics of X-RADIATION in terms of fractions of PRIMARY RADIATION and SCATTERED RADIATION depend on the position and nature of any ADDED FILTER or PHANTOM. It is therefore obvious, that AIR KERMA measurements in such RADIATION BEAMS need careful consideration.

Clauses 5 and 6 deal with RADIATION CONDITIONS which are essentially free of SCATTERED RADIATION. Due to the spatial homogeneity of these RADIATION CONDITIONS, the APPLICATION DISTANCE does not influence the RADIATION CONDITIONS to a significant extent. These RADIATION CONDITIONS are called RADIATION QUALITIES.