

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

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee HCC/71, X-ray tubes, upon which the following bodies were represented:

- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- British Institute of Radiology
- College of Radiographers
- Department of Health
- Disablement Services Authority
- Institute of Physical Sciences in Medicine (Ipsm)

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National foreword

This British Standard has been prepared by Technical Committee HCC/71 and is the English language version of EN 61267:1995 *Medical diagnostic X-ray equipment — Radiation conditions for use in the determination of characteristics*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 1267 published by the International Electrotechnical Commission (IEC).

Cross-references

Publication referred to	Corresponding British Standard
EN 60601-1:1990 (IEC 601-1:1988)	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i>
HD 501 S1:1988 (IEC 788:1984)	BS 6641:1985 <i>Glossary of medical radiology terms</i>
IEC 1223-1:1993	BS 7725 <i>Evaluation and routine testing in medical imaging departments</i> Part 1:1994 <i>General</i>

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 24, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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English version

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

(IEC 1267:1994)

Équipement 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)

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CENELEC

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

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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
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- 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, Annex A and Annex ZA are normative and Annex B and Annex C are informative.

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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:

- 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;
- 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.

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*

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.

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).