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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis

Caractéristiques électriques et de charge des gaines équipées pour diagnostic médical

IEC 60613:2010

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ELECTRICAL AND LOADING CHARACTERISTICS OF X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS

FOREWORD

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International Standard IEC 60613 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee TC 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60613, published in 1989. It constitutes a technical revision. This third edition has been adapted to apply to the present technology.

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

FDIS	Report on voting
62B/774/FDIS	62B/780/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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In this standard, the following print types are used:

– requirements and definitions: roman type.
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPS.

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ELECTRICAL AND LOADING CHARACTERISTICS OF X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS

1 Scope

This International Standard applies to X-RAY TUBE ASSEMBLIES either with a rotating ANODE X-RAY TUBE or a stationary ANODE X-RAY TUBE, intended for use in medical diagnosis.

For an X-RAY TUBE HEAD, its X-RAY TUBE ASSEMBLY aspects are also within the scope.

This International Standard covers performance-related definitions and conditions of electrical and LOADING characteristics of X-RAY TUBE ASSEMBLIES in relation to their behaviour during and after energization and, where appropriate, methods of presentation and measurement of these characteristics. This International Standard is therefore relevant for the MANUFACTURER and the RESPONSIBLE ORGANIZATION.

NOTE "Measurement" in this standard is always related to practical use. Consequently, "measurement" is meant to consume only a negligible part of the life of the X-RAY TUBE ASSEMBLY.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (available only in English)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC/TR 60788:2004, IEC 60601-1:2005 and IEC 60601-1-3:2008 and the following apply.

3.1
X-RAY TUBE VOLTAGE
potential difference applied to an X-RAY TUBE between the ANODE and the CATHODE. Usually X-RAY TUBE VOLTAGE is expressed by its peak value in kilovolts (kV)

[IEC 60601-1-3:2008, 3.88]

3.2
NOMINAL X-RAY TUBE VOLTAGE
highest permitted X-RAY TUBE VOLTAGE for SPECIFIC operating conditions

[IEC 60601-1-3:2008, 3.42]

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NOTE 1 For different operating conditions of the X-RAY TUBE, for example continuous operation, intermittent operation, short-time operation, different types of X-RAY TUBE HOUSINGS, there may be different values of the above NOMINAL X-RAY TUBE VOLTAGE.

NOTE 2 Additionally, values may be given for the highest permitted potential difference between ANODE and earth and between CATHODE and earth.

3.3
X-RAY TUBE CURRENT
electric current of the ELECTRON beam incident on the TARGET of an X-RAY TUBE. Usually, the X-RAY TUBE CURRENT is expressed by its mean value in milliamperes (mA)

[IEC 60601-1-3:2008, 3.85]

NOTE See Annex B for further considerations.

3.4
CATHODE EMISSION CHARACTERISTIC
dependence of the X-RAY TUBE CURRENT on variables, for example FILAMENT CURRENT, X-RAY TUBE VOLTAGE

3.5
ENVELOPE
vacuum-wall of the X-RAY TUBE

3.6
ENVELOPE CURRENT
electric current, flowing via a conducting part of an ENVELOPE

3.7
ENVELOPE VOLTAGE
potential difference between an X-RAY TUBE-conducting ENVELOPE part and earth

3.8
LOADING
in an X-RAY GENERATOR, act of supplying electrical energy to the ANODE of an X-RAY TUBE

[IEC 60601-1-3:2008, 3.34]

3.9
X-RAY TUBE LOAD
electrical energy supplied to an X-RAY TUBE expressed by a combination of values of LOADING FACTORS

3.10
LOADING FACTOR
factor influencing by its value the X-RAY TUBE LOAD, for example X-RAY TUBE CURRENT, LOADING TIME, CONTINUOUS ANODE INPUT POWER, X-RAY TUBE VOLTAGE and PERCENTAGE RIPPLE

[IEC 60601-1-3:2008, 3.35]

3.11
LOADING TIME
time determined according to a SPECIFIC method, during which the ANODE INPUT POWER is applied to the X-RAY TUBE

[IEC 60601-1-3:2008, 3.37]

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3.12
CYCLE TIME
for a series of single LOADINGS: time interval from the beginning of a LOADING to the beginning of the next, identical LOADING

for a series of serial LOADINGS: time interval from the beginning of a serial LOADING to the beginning of the next, identical serial LOADING

3.13
ANODE INPUT POWER
power applied to the ANODE of an X-RAY TUBE to produce X-RADIATION

3.14
NOMINAL ANODE INPUT POWER
highest constant ANODE INPUT POWER that can be applied for a single X-RAY TUBE LOAD in a SPECIFIC LOADING TIME and under SPECIFIED conditions

3.15
NOMINAL RADIOGRAPHIC ANODE INPUT POWER
NOMINAL ANODE INPUT POWER which can be applied for a single X-RAY TUBE LOAD with a LOADING TIME of 0,1 s and a CYCLE TIME of 1,0 min, for an indefinite number of cycles

NOTE 1 In this application, RADIOSCOPY is not applied.

NOTE 2 With this definition mammographic and dental X-ray are included, see A.3.3 in Annex A.

3.16
NOMINAL CT ANODE INPUT POWER
NOMINAL ANODE INPUT POWER which can be applied for a single X-RAY TUBE LOAD with a LOADING TIME of 4 s and a CYCLE TIME of 10 min, for an indefinite number of cycles

3.17
X-RAY TUBE ASSEMBLY INPUT POWER
mean power applied to an X-RAY TUBE ASSEMBLY for all purposes before, during and after LOADING, including power applied to the stator of a rotating ANODE X-RAY TUBE, to the filament and to any other device included in the X-RAY TUBE ASSEMBLY

3.18
NOMINAL CONTINUOUS INPUT POWER
SPECIFIED highest X-RAY TUBE ASSEMBLY INPUT POWER, which can be applied to an X-RAY TUBE ASSEMBLY continuously

3.19
CONTINUOUS ANODE INPUT POWER
SPECIFIED highest ANODE INPUT POWER, which can be applied to the ANODE continuously

NOTE 1 CONTINUOUS ANODE INPUT POWER may be determined by subtracting all power other than the ELECTRON beam power, such as filament heating, ANODE drive, from the NOMINAL CONTINUOUS INPUT POWER.

NOTE 2 If not SPECIFIED otherwise, CONTINUOUS ANODE INPUT POWER is the referenced LOADING FACTOR for determining the LEAKAGE RADIATION.

3.20
CT SCAN POWER INDEX
CTSPI
characteristic of an X-RAY TUBE ASSEMBLY intended for use in COMPUTED TOMOGRAPHY for a SPECIFIED range of LOADING TIMES for single LOADINGS, for a given CYCLE TIME, as follows

$$CTSPI = \frac{1}{(t_{max} - t_{min})} \int_{t_{min}}^{t_{max}} P(t)\,\mathrm{d}t$$

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where

t_{max} is the upper limit of the LOADING TIME in seconds,

t_{min} is the lower limit of the LOADING TIME in seconds, and

$P(t)$ is the function representing the SINGLE LOAD RATING in kilowatts

NOTE The CTSPI represents the effective power for PATIENT throughput in CT scanning.

3.21
NOMINAL CT SCAN POWER INDEX
NOMINAL CTSPI
CTSPI, calculated for a lower limit of the LOADING TIME of 1 s, an upper of the LOADING TIME of 25 s and a CYCLE TIME of 10 min

3.22
RADIOGRAPHIC RATINGS
for the operation of an X-RAY TUBE, SPECIFIED combinations of conditions and LOADING FACTORS, under which the SPECIFIED limits of loadability of the X-RAY TUBE are attained

3.23
SINGLE LOAD RATING
highest permitted X-RAY TUBE LOAD given by a relationship between constant ANODE INPUT POWER and LOADING TIME for one LOADING under SPECIFIED conditions

3.24
SERIAL LOAD RATING
highest permitted X-RAY TUBE LOAD given by the relationship between ANODE INPUT POWER and LOADING TIME for the total of a SPECIFIED series of individual X-RAY TUBE LOADS with SPECIFIED LOADING FACTORS under SPECIFIED conditions

4 Presentation of the electrical characteristic

4.1 X-RAY TUBE VOLTAGE

The X-RAY TUBE VOLTAGE shall be given as the peak value, in kilovolts.

4.2 NOMINAL X-RAY TUBE VOLTAGE

The NOMINAL X-RAY TUBE VOLTAGE shall be given as the peak value, in kilovolts.

4.3 X-RAY TUBE CURRENT

The X-RAY TUBE CURRENT shall be given as the average value in milliamperes.

4.4 CATHODE EMISSION CHARACTERISTIC

CATHODE EMISSION CHARACTERISTICS are given as a family of curves in which the X-RAY TUBE CURRENT is shown as a function of the FILAMENT CURRENT and, if appropriate, of further characteristics of the CATHODE, each curve corresponding to an X-RAY TUBE VOLTAGE while specifying its waveform, and other factors as appropriate. If appropriate, the relationship between FILAMENT CURRENT and filament voltage shall be indicated and also its dependence on other characteristics of the CATHODE.

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4.5 ENVELOPE characteristics

4.5.1 ENVELOPE CURRENT

If the ENVELOPE CURRENT is to be stated, it shall be given as the percentage value of X-RAY TUBE CURRENT under SPECIFIED conditions.

4.5.2 ENVELOPE VOLTAGE

If the ENVELOPE VOLTAGE is to be stated, it shall be given in kilovolts with respect to earth.

5 LOADING of an X-RAY TUBE

5.1 LOADING TIME

5.1.1 Units

The LOADING TIME shall be given in seconds.

5.1.2 Measurement

LOADING TIME is measured as the time interval between:

– the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and

– the instant at which it finally drops below the same value.

If LOADING is controlled by electronic switching of the HIGH VOLTAGE, using a grid in an electronic tube or in the X-RAY TUBE, the LOADING TIME may be determined as the time interval between the instant when the TIMING DEVICE generates the signal to start the IRRADIATION and the instant when it generates the signal to terminate the IRRADIATION.

If LOADING is controlled by simultaneous switching in the primaries of both the high-voltage circuit and the heating supply for the filament of the X-RAY TUBE, the LOADING TIME shall be determined as the time interval between the instant when the X-RAY TUBE CURRENT first rises above 25 % of its maximum value and the instant when it finally falls below the same value.

NOTE 1 See also definition 3.11.

NOTE 2 The LOADING TIME is preferably measured at the tube input to minimise the influence of HV-cable-capacitance.

NOTE 3 For field-testing, a reasonable approximation of the LOADING TIME can be obtained by measuring the IRRADIATION TIME, for which the SPECIFIC method according to the definition in IEC 60601-1-3:2008 is chosen in this International Standard as the time period during which the AIR KERMA RATE exceeds 50 % of its peak value.

5.2 CYCLE TIME

The CYCLE TIME shall be given in minutes or seconds, as appropriate.

6 Input power

6.1 ANODE INPUT POWER

The ANODE INPUT POWER shall be given in kilowatts for SPECIFIED conditions of LOADING.

6.2 NOMINAL ANODE INPUT POWER

The NOMINAL ANODE INPUT POWER shall be given in kilowatts.

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6.3 NOMINAL RADIOGRAPHIC ANODE INPUT POWER

The NOMINAL RADIOGRAPHIC ANODE INPUT POWER shall be given in kilowatts.

6.4 NOMINAL CT ANODE INPUT POWER

The NOMINAL CT ANODE INPUT POWER shall be given in kilowatts.

6.5 X-RAY TUBE ASSEMBLY INPUT POWER

The X-RAY TUBE ASSEMBLY INPUT POWER shall be given in watts.

6.6 NOMINAL CONTINUOUS INPUT POWER

The NOMINAL CONTINUOUS INPUT POWER shall be given in watts.

Unless otherwise SPECIFIED, the ambient temperature shall be between 20 °C and 25 °C.

6.7 CONTINUOUS ANODE INPUT POWER

The CONTINUOUS ANODE INPUT POWER shall be given in watts.

6.8 CT SCAN POWER INDEX (CTSPI)

The CT SCAN POWER INDEX shall be given in kilowatts.

6.9 NOMINAL CT SCAN POWER INDEX (NOMINAL CTSPI)

The NOMINAL CT SCAN POWER INDEX shall be given in kilowatts.

7 RADIOGRAPHIC RATINGS

7.1 General

RADIOGRAPHIC RATINGS shall provide application-relevant parametric information on LOADING FACTORS, in any form of presentation (tables, graphs ...) which is supporting the application. If a NOMINAL ANODE INPUT POWER is SPECIFIED, the RADIOGRAPHIC RATINGS shall at least encompass the set of LOADING FACTORS pertinent to the SPECIFIED NOMINAL ANODE INPUT POWER.

7.2 SINGLE LOAD RATING

The SINGLE LOAD RATING shall be presented as curves or as a table of numerical values showing constant ANODE INPUT POWER as a function of LOADING TIME and CYCLE TIME for appropriate LOADING FACTORS, for example NOMINAL FOCAL SPOT VALUE, ANODE SPEED and others.

7.3 SERIAL LOAD RATING

SERIAL LOAD RATINGS shall be presented as curves or as a table of numerical values with values of the CYCLE TIME and the appropriate LOADING FACTORS, for example, ANODE INPUT POWER for an individual X-RAY TUBE LOAD, LOADING TIME of an individual X-RAY TUBE LOAD, total number of LOADINGS or the duration of a series of LOADINGS, number of individual X-RAY TUBE LOADS per second.

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8 Presentation of data

If single data values are presented in compliance with this International Standard, such values shall be designated as follows:

<Term according to Clause 3> <value> <unit> IEC 60613:2010

If graphs or tables are presented in compliance with this International Standard, a reference to IEC 60613:2010 shall be given.

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Annex A
(informative)

Rationale and historical background

A.1 Overview

The purpose of this annex is to state the general objectives and approach used in creating the 3rd edition of this standard, and to clarify the inclusion of those items which are substantially new to this edition, as well as to clarify why some items are no longer described.

A.2 History: basis of 1st and 2nd editions

The subject matter of these earlier editions was the electrical and thermal ratings of medical X-RAY TUBE ASSEMBLIES and their LOADING characteristics. Therefore, the thermal/electrical construction and operating mechanisms of X-RAY TUBES existing at the time of the earlier editions of the standard had a significant impact on the content of those early versions. Historically, medical X-RAY TUBES have been primarily constructed with glass ENVELOPES which act as the insulating support between the electrically charged ANODE and CATHODE electrodes. As such, it was not necessary or practical to define the electrical potential of this insulating ENVELOPE, which takes on an ambiguous charge state at any particular point of its surface. It was sufficient to state the potential difference between the ANODE and the CATHODE, or the potential of these electrodes relative to earth. Regarding the thermal/LOADING characteristics, most medical rotating ANODE X-RAY TUBES were constructed in such a way as to temporarily store the heat generated in the bremsstrahlung process and then dissipate it through the very non-linear thermal RADIATION process. Further, at the time of the earlier editions, applications were primarily directed at RADIOGRAPHY. In the meantime, vascular and CT applications, implying different LOADING conditions (relatively long exposures, heavy PATIENT throughput) have to be considered.

A.3 Problems and solutions: objectives of the 3rd edition

A.3.1 General

Technical advancements in X-RAY TUBE design have lead to improvements, particularly in the thermal operation of X-RAY TUBES that have made the application of the previous edition of the standard inadequate. The main advancements and their impacts on the application of the standard are described below.

A.3.2 Advent of metal/ceramic ENVELOPE construction

One of the advancements that have been widely adopted in the industry, especially for high-power X-RAY TUBES, is the use of metallic ENVELOPES, often with ceramic, i.e. non-glass insulators. These ENVELOPES can carry a substantial fraction of the overall X-RAY TUBE CURRENT during operation as backscattered ELECTRONS from the TARGET are collected on the inner surfaces of the metallic ENVELOPE and conducted back through to the HIGH-VOLTAGE GENERATOR. Because it is important to know what the intended electrical connection scheme is between the tube and generator, this edition of the standard has added a section of terms and definitions specifically related to the ENVELOPE'S electrical configuration.

A.3.3 Thermal ratings definitions moved away from heat-content based definitions

The older editions of the standard described the tube's thermal performance in terms of characteristics such as the heat storage content, the heat dissipation rate, heating curves and cooling curves. Before the widespread availability of computers integrated into X-ray imaging systems, this data was intended to be used by the technologist to calculate the X-RAY TUBE'S

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