

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS Z 4102 : 2005

(JIRA/JSA)

X-ray tube for medical use

ICS 11.040.50

Reference number : JIS Z 4102 : 2005 (E)

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry, through deliberations at the Japanese Industrial Standards Committee as a result of proposal for revision of Japanese Industrial Standard submitted by Japan Industries Association of Radiological Systems (JIRA)/Japanese Standards Association (JSA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

Consequently, JIS Z 4102 : 1994 is replaced with this Standard.

In order to conform to the International Standard, this revision has been prepared based on IEC 60336 : 1993 *X-ray tube assemblies for medical diagnosis—Characteristics of focal spots*, 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* and IEC 60613 : 1989 *Electrical thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis*.

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Date of Establishment: 1962-03-01

Date of Revision: 2005-03-25

Date of Public Notice in Official Gazette: 2005-03-25

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Medical Equipment

JIS Z 4102 : 2005, First English edition published in 2005-08

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

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X-ray tube for medical use

Introduction This Japanese Industrial Standard has been prepared based on the third edition of IEC 60336 *X-ray tube assemblies for medical diagnosis—Characteristics of focal spots* published in 1993, the first edition of IEC 60601-2-28 *Medical electrical equipment—Part 2 : Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis* published in 1993 and the second edition of IEC 60613 *Electrical thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis* published in 1989 with some modifications of technical contents.

Portions given sidelines or dotted underlines are the matters modified from the original International Standard. A list of modifications with the explanations is given in annex (informative).

1 Scope This Standard specifies an X-ray tube for diagnosis, an X-ray tube for medical X-ray CT, and an X-ray tube for therapy.

Remarks : The International Standards corresponding to this Standard are as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

IEC 60336 : 1993 *X-ray tube assemblies for medical diagnosis — Characteristics of focal spots* (MOD)

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* (MOD)

IEC 60613 : 1989 *Electrical thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis* (MOD)

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS B 7516 *Metal rules*

JIS C 1102-2 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 2: Special requirements for ammeters and voltmeters*

JIS T 0601-1 *Medical electrical equipment—Part 1: General requirements for safety*

Remarks : IEC 60601-1 : 1988 *Medical electrical equipment — Part 1: General requirements for safety*, Amendment 1 : 1991 and Amendment 2 : 1995 are identical with the said standard.

JIS Z 4005 *Medical radiology—Terminology*

Remarks : IEC 60788 : 1984 *Medical radiology—Terminology* is identical with the said standard.

JIS Z 4511 *Methods of calibration for exposure meters and dose-equivalent meters*

JIS Z 4701 *General rules for medical X-ray equipment*

JIS Z 4702 *General requirements for high-voltage generators of medical X-ray apparatus*

Remarks : IEC 60601-2-7 : 1998 *Medical electrical equipment—Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators* is equivalent to the said standard.

JIS Z 4711 *Mono tank X-ray generators for diagnostic use*

JIS Z 4752-2-1 *Evaluation and routine testing in medical imaging departments—Part 2-1: Constancy tests : Film processors*

JIS Z 4916 *Test charts for resolution characteristics of X-ray equipment*

3 Definitions For the purposes of this Standard, the definitions in JIS Z 4005 and JIS Z 4701 and the following definitions apply. The [bracketed] terms were used in the previous Japanese Industrial Standards.

- a) **medical X-ray tube** vacuum tube for medical use where the electron beam from the cathode is accelerated by the electrical field and strikes the target, and its impact generates X-rays (hereafter referred to as an “X-ray tube”). The target is usually contained in the anode.
- b) **grid-controlled X-ray tube** X-ray tube with the grid electrode which controls tube current
- c) **stereo X-ray tube** X-ray tube which has plural focal spots distanced from each other, and is used in such a radiographic manner that the same subject is radiographed with these two focal spots switched and the stereo radiograms can be produced using the images thus obtained
- d) **effective focal spot** vertical projection of the actual focal spot to a reference plane (hereafter referred to as a “focal spot”).

The designation of an **effective focal spot** is usually the absolute number expressed in millimeters of its size (width) in the perpendicular direction to an X-ray tube axis and of its size (length) in the parallel direction to an X-ray tube axis.

- e) **blooming value** value of the ratio of two resolution limits acquired according to specific loading conditions, which shows the characteristic of the **effective focal spot** of an X-ray tube
- f) **MTF (modulation transfer function)** the Fourier transform of a line spread function. In a symmetrical line spread function, a modulation transfer function (MTF) is the Fourier transform which is normalized using the following formulae.

$$M(\nu) = \frac{\int_{-\infty}^{\infty} L(x) \cos(2\pi\nu x) dx}{\int_{-\infty}^{\infty} L(x) dx}$$

where, ν : spatial frequency

L : line spread function

x : lateral coordinates

M : quantifier

- g) **target** portion of an X-ray tube where an impact is given by the electron beam in order to generate X-rays
- h) **target angle** angle which a real focal spot plane and a reference axis make
- i) **focusing electrode** portion of a cathode where electronic convergence is performed
- j) **X-ray tube voltage** potential difference applied to an X-ray tube between the anode and the cathode (hereafter referred to as “tube voltage”). Usually, tube voltage shall be given as the peak value in kilovolt (kV).
- k) **nominal maximum tube voltage [maximum operating tube voltage] (nominal X-ray tube voltage)** highest maximum tolerance of tube voltage for the specified⁽¹⁾ operating condition and voltage waveform. Unless otherwise specified⁽¹⁾, this value shall not be exceeded for any operating conditions.
Note⁽¹⁾ The word “specified” means “specified by a manufacturer in the accompanying documents”.
- l) **X-ray tube voltage for charging** potential difference applied to an X-ray tube between the anode and the cathode of the grid-controlled X-ray tube assembly to be used for high-voltage circuit at the time of charge of the high-voltage capacitor
- m) **nominal maximum charge tube voltage [maximum operating charge tube voltage]** highest permitted value of charge tube voltage
- n) **reverse voltage** tube voltage when negative potential against the cathode is applied to the anode. Reverse voltage is used to distinguish from tube voltage when positive potential is applied to the anode, and is given as the peak value in kilovolt (kV).
- o) **nominal maximum reverse voltage [maximum operating reverse voltage]** highest permitted value of reverse voltage
- p) **X-ray tube current** the current of the electron beam reaching the target of an X-ray tube (hereafter referred to as “tube current”). Tube current shall be given as the average value in milliamperes (mA). However, in the radiography performed using the capacitor type X-ray generator, the peak value shall be given in milliamperes peak (mA_p).

Remarks : The tube current is generally measured at the anode side. However, when the X-ray tube of the metal envelope is used, the current flowing through the cathode side circuit shall be tube current.

- q) X-ray tube current characteristics relation between the tube current and the filament current under the specified⁽¹⁾ X-ray tube loading factor
- r) filament characteristics relation of the voltage applied to the filament and the filament current

Remarks : the maximum tolerance of the filament current under the specified⁽¹⁾ operating condition is called maximum filament current. Usually, the long-time use filament current and the short-time use filament current are different from each other.

- s) filament current in an X-ray tube, the current supplied to the filament in order to control the thermo electronic emission from the cathode
- t) loading act of supplying electrical energy to the anode of an X-ray tube
- u) X-ray tube load electrical energy supplied to an X-ray tube expressed by a combination of values of X-ray tube loading factor
- v) X-ray tube loading factor factor influencing the X-ray tube load value, for example, X-ray tube current, loading time, equivalent anode input power, X-ray tube voltage, and percentage ripple
- w) loading time time, determined by a specific method ⁽²⁾, during which the anode input power is applied to the X-ray tube

Note ⁽²⁾ See JIS Z 4702 [3 Definition x) Radiographic time].

- x) anode input power [X-ray tube input power] electric power applied to the anode of an X-ray tube to produce X-rays. This electric power is given by the following formulae

$$P = U \times I \times f \times 10^{-3}$$

where, P : anode input power (kW)

U : tube voltage (kV)

I : tube current (mA)

f : the constant which is determined by the percentage ripple of tube voltage. Where,

$f = 1.0$: for a percentage ripple 10 % or less

$f = 0.95$: for a percentage ripple over 10% to and including 25 %

$f = 0.74$: for a percentage ripple 25 % or less

Remarks : A tube-voltage percentage ripple is given by the following formulae.

$$\Delta U = \frac{U_{\max} - U_{\min}}{U_{\max}} \times 100$$

where, ΔU : **percentage ripple (%)**

$U_{\max}$: **the peak value of a tube-voltage waveform**

$U_{\min}$: **the minimum value of a tube-voltage waveform (however, the spike waveform of a voltage stabilizer is excluded.)**

- y) **nominal anode input [maximum input]** the maximum tolerance of anode input power in the specified loading time and under the specified⁽¹⁾ operating condition. The operating conditions mean the designation of a focal spot, tube voltage, tube-voltage waveform, and anode speed of a rotating anode X-ray tube, etc.
- z) **heat unit** special unit showing the input of an X-ray tube. The unit symbol for the heat unit shall be HU and a heat unit value is calculated by the following formulae according to a high-voltage transformer assembly.

In addition, meaning of symbols used here shall be as follows:

U : **tube voltage (kV)**

I : **tube current (mA)**

t : **loading time (s)**

C : **capacitor capacity (μ F)**

- 1) In the case of 1-peak type or 2-peak type circuit

$$\text{HU value} = U \times I \times t$$

$$\text{HU value per 1 s} = U \times I$$

- 2) In the case of 12-peak type circuit or the circuit having equivalent **percentage ripple**

$$\text{HU value} = U \times I \times t \times 1.35$$

$$\text{HU value per 1 s} = U \times I \times 1.35$$

- 3) In the case of constant voltage or the inverter circuit

$$\text{HU value} = U \times I \times t \times 1.41$$

$$\text{HU value per 1 s} = U \times I \times 1.41$$

- 4) In the case of a capacitor type

$$\text{HU value} = 0.71 \times C \times (U_1^2 - U_2^2)$$

where U_1 expresses the **tube voltage** at the commencement of discharge, and U_2 expresses the **tube voltage** at the time of electric discharge termination.

Remarks : Conversion between HU value and other units is performed noting that 1 HU is equivalent to 0.71 J.

- aa) **equivalent anode input power** values of the anode input power which, if applied continuously under the specified⁽¹⁾ ambient conditions, would maintain a specific level of anode heat content. With respect to radiographic ratings, the electric power which maintains the highest level of initial anode heat content for which the radiographic rating is valid.
- ab) **X-ray tube maximum continuous input [long-time maximum input]** maximum of the anode input power which can be continuously applied under the specified⁽¹⁾ conditions in the range which does not exceed a maximum anode heat content
- ac) **maximum single loading ratio [short-time maximum input]** maximum of the X-ray tube load which is determined under the specified⁽¹⁾ conditions as a relationship between anode input power and loading time for one loading. Unless otherwise specified⁽¹⁾, it refers to the value in the cold condition.

Remarks : In this Standard, the cold condition shall be the condition where the anode heat content is zero in an anode cooling curve chart.

- ad) **X-ray tube repeatable maximum input** highest permitted X-ray tube load given by the relationship between anode input power and loading time for a total of a specified series of individual X-ray tube loads according to the specified⁽¹⁾ X-ray tube loading factors
- ae) **anode heat content** instantaneous value of the heat contained in the anode of an X-ray tube accumulated during, or retained after, loading
- af) **maximum anode heat capacity [anode accumulating heat content]** maximum of the anode heat content permitted
- ag) **anode heat up curve** curve showing the anode heat content as a function of loading time for specified⁽¹⁾ anode input power
- ah) **anode cooling curve** curve showing the anode heat content as a function of time with zero anode input power, after loading until the anode heat content is equal to the maximum anode heat content

Remarks : In this time sequence, the rate that an anode heat content decreases is called anode cooling rate, and its maximum value is called anode maximum cooling rate.

- ai) **rated anode speed** anode speed required when applying the anode input power to an X-ray tube
- aj) **starting time** time required for the anode to reach rated anode speed from a state of rest under the specified⁽¹⁾ conditions
- ak) **braking time** time required for the anode to be braked from rated anode speed to the specified⁽¹⁾ revolving speed under the specified⁽¹⁾ conditions
- al) **X-ray radiation angle** vertical angle of the maximum utilization beam
- am) **reference axis** with respect to an X-ray tube, the specified ⁽¹⁾ axis which passes through a centre of focal spot and serves as a reference

- an) **reference plane** with respect to the **effective focal spot** of X-ray tube assemblies, the plane which includes an intersecting point of a **reference axis** with an **actual focal spot**, and which is perpendicular to a **reference axis**
- ao) **permanent filtration** **quality equivalent filtration** by means of the substance which cannot be removed. **Permanent filtration** is the basis of the specified⁽¹⁾ **tube voltage** and **tube-voltage** waveform, and is expressed by the thickness of the reference substance which gives the same **quality of radiation** by conversion into the first **half-value layer**.
- ap) **film base plus fog density** the optical radiogram density of the controlled film developed for the purpose of constancy test of X-ray equipment, particularly the density of the portion which is not exposed to the light of a sensitometer (this definition shall be as specified in JIS Z 4752-2-1.)
- aq) **net optical density** the density which is net with the **film base plus fog density** being subtracted

4 Classification and model name

4.1 Classification

4.1.1 **X-ray tube for diagnosis** The classification and model name of an X-ray tube for diagnosis shall be as follows:

- a) **Fixed anode X-ray tube** It consists of each combination of the following items.
 - 1) **According to control** 2-pole type, grid-controlled type
 - 2) **Number of focal spots** Single focal spot type, multiple focal spot type
 - 3) **Designation of focal spot** 2.5, 2.0, 1.5, 1.0, 0.8 and 0.6 shall be a standard.
- b) **Rotating anode X-ray tube** It consists of each combination of the following items.
 - 1) **According to control** 2-pole type, grid-controlled type
 - 2) **Number of focal spots** Single focal spot type, multiple focal spot type
 - 3) **Designation of focal spot** 2.0, 1.5, 1.2, 1.0, 0.8, 0.6, 0.3, 0.2 and 0.1 shall be a standard.
 - 4) **Anode speed** Ordinary rotation type, high-speed rotation type

Remarks 1 X-ray tubes for diagnosis contain the X-ray tubes of a particular application. Therefore, especially when required, it is allowed to include to a class where the intended use is limited.

Example : X-ray tube for mammography, X-ray tube for stereo radiography, etc.

Remarks 2 With respect to **anode speed**, the ordinary rotation shown here means rotation speed which is driven by the stator power supply of frequency 50 Hz or 60 Hz of a power supply (commercial), and it shall be $2\,700\text{ min}^{-1}\{\text{rpm}\}$ or more for steady state 50 Hz, and $3\,200\text{ min}^{-1}\{\text{rpm}\}$ or more for 60 Hz. The high-speed rotation means the rotation where the

driving frequency of a power supply exceeds 60 Hz of commercial frequency.

4.1.2 X-ray tube for medical X-ray CT The class and model name of an X-ray tube for medical X-ray CT shall be as follows:

- a) **X-ray tube for fixed anode medical X-ray CT** It consists of combination of the following items.
 - 1) **According to control** 2-pole type, grid-controlled type
 - 2) **Number of focal spots** Single focal spot type, multiple focal spot type
 - 3) **Designation of focal spots** 2.0, 1.5, 1.2, 1.0, 0.8 and 0.6 shall be a standard.
- b) **X-ray tube for rotating anode medical X-ray CT** It consists of combination of the following items:
 - 1) **According to control** 2-pole type, grid-controlled type
 - 2) **Number of focal spots** Single focal type, multiple focal spot type
 - 3) **Designation of focal spots** 2.0, 1.5, 1.2, 1.0, 0.8 and 0.6 shall be a standard.
 - 4) **Anode speed** Ordinary revolution type, high-speed revolution type

Remarks : Ordinary revolution type and high-speed revolution type shall be specified in remarks 2 of 4.1.1 b) 4).

4.1.3 X-ray tube for therapy The classification and model name of an X-ray tube for therapy shall be as follows:

- a) **X-ray tube for deep radiotherapy** It is classified by the highest operating tube voltage.

Example : For 200 kV, for 250 kV
- b) **X-ray tube for superficial radiotherapy** It is classified by the highest operating tube voltage and a radiation aperture filter medium.
 - 1) **Maximum operating tube voltage**

Example : For 10 kV, for 25 kV, for 50 kV
 - 2) **Radiation aperture filter medium**

Example : Beryllium

4.2 Model name Model name shall be constituted by class, and expressed with the combination of the following character and number.

1st item	2nd item	3rd item – 4th item	5th item
“Character”	“Character”	“Number-number”	“Character”

The character and number of each item shall be as follows:

- a) The 1st item shall express the intended use of an X-ray tube as shown in table 1.
- b) The 2nd item shall express the structure of an X-ray tube as shown in table 2. However, a grid-controlled type shall express what is used in combination with a

capacitor type X-rays high-voltage generator. A stereo type shall contain a grid-controlled stereo X-ray tube.

With respect to a rotating anode type multiple focal spot X-ray tube, F shall be omitted.

Table 1 Classification of model name by the intended use

Classification by the intended use	Character of the 1st item
Fixed anode X-ray tube for diagnosis	D
Rotating anode X-ray tube for diagnosis	R
Fixed anode X-ray tube for medical X-ray CT	C
Rotating anode X-ray tube for medical X-ray CT	K
X-ray tube for therapy	T

Table 2 Classification of model name by structure

Classification by structure	Character of the 2nd item
Multiple focal spot type	F
Grid-controlled type	G
Stereo type	S

- c) The 3rd item is the value of nominal maximum tube voltage (nominal X-ray tube voltage) expressed in kilovolt (kV) value.
- d) The 4th item is, for diagnosis, the value of nominal anode input power [see clause 3 y) and 5.1 n)] in each focal spot expressed in kilowatts (kW), and it is, for therapy, the value of long-time maximum input [see clause 3 ab) and 5.1 o)] expressed in watts (W).
- e) The 5th item expresses aperture material of an X-ray tube with the following character. However, aperture material of ordinary glass is omitted.

Equipped with a beryllium aperture B

Remarks : An example of model name is as follows: For a **grid-controlled rotating anode X-ray tube** with a beryllium aperture, the **nominal maximum tube voltage (nominal X-ray tube voltage)** of 80 kV, the **nominal anode input power** of 20 kW and 50 kW at a small focal spot and a large focal spot, respectively; RG80—20/50B.

5 Rating

5.1 X-ray tube for diagnosis The rating shall be shown with the material, numerical value, etc. of the following items. Unrelated items depending on the class of X-ray tube may be omitted.

Remarks : The units W and J may be accompanied by values of HU/s and HU, respectively.

- a) **Designation of focal spots and focal reference axis** Designation of focal spots shall be shown with the size of width $\times$ length.

Remarks : When the designation of width and length is the same, either of them may be shown.

A reference axis is shown in the outline drawing of accompanying documents.

- b) **Quality of target material**
- c) **Target angle ($^{\circ}$)**
- d) **Nominal maximum tube voltage (nominal X-ray tube voltage) (kV)**
- e) **Nominal maximum charge voltage (kV)**
- f) **Nominal maximum reverse voltage (kV)**
- g) **Nominal maximum anode—earth voltage (kV)**
- h) **Nominal maximum anode—earth reverse voltage (kV)**
- i) **Nominal maximum cathode—earth voltage (kV)**
- j) **Nominal maximum cathode—earth reverse voltage (kV)**
- k) **Maximum filament—grid voltage (V)**
- l) **Tube current interruption grid voltage (V)**

Remarks : Potential difference against filament

- m) **Filament heating**
- 1) **Maximum filament current (A)**
- 2) **Maximum filament voltage (V)**

Remarks : The maximum filament voltage shown here is the maximum value of the filament voltage at the **maximum filament current**.

- n) **Nominal anode input power (kW)**

Remarks : It is the allowable maximum value of **anode input power** of 0.1 s for a rotating anode X-ray tube, and of 1 s for fixed anode X-ray tube.

- o) **X-ray tube maximum continuous input (W)**
- p) **Maximum single load rating**
- q) **Maximum anode heat capacity (J)**
- r) **Anode heat up curve**

Remarks : With **anode input power (W)** being a parameter, the curve shows the **anode heat content (J)** as a function of **loading time (s or min)**.

- s) **Anode cooling curve**

Remarks : With **anode input power (W)** being at zero, the curve shows the **anode heat content (J)** as a function of **loading time (s or min)**.

- t) **Anode maximum cooling rate (W)**
- u) **Rated anode speed (min^{-1}) {rpm}**

- v) Starting time (s)
- w) Braking time (s)
- x) X-ray radiation angle (°)
- y) Permanent filtration (mmCu, mmAl, mmBe)
 - 1) With respect to X-ray tube used mainly for diagnosis, it is expressed by the thickness of aluminum for nominal maximum tube voltage (nominal X-ray tube voltage) below 150 kV, and, by thickness of copper for X-ray tube exceeding 150 kV.
 - 2) With respect to the X-ray tube where the window of X-ray tube consists only of beryllium, it is expressed by the thickness of beryllium or aluminum.

z) Cooling system

aa) Mass (kg)

5.2 X-ray tube for medical X-ray CT The rating of an X-ray tube for diagnosis shall apply.

5.3 X-ray tube for therapy The rating shall be shown with the material, numerical value, etc. of the following items. Unrelated items depending on the class of X-ray tube may be omitted.

- a) Quality of target material
- b) Target angle (°)
- c) Nominal maximum tube voltage (nominal X-ray tube voltage) (kV)
- d) Nominal maximum reverse voltage (kV)
- e) Nominal maximum anode—earth voltage (kV)
- f) Nominal maximum anode—earth reverse voltage (kV)
- g) Nominal maximum cathode—earth voltage (kV)
- h) Nominal maximum cathode—earth reverse voltage (kV)
- i) Maximum tube current at nominal maximum tube voltage (mA)
- j) Filament heating
 - 1) Maximum filament current (A)
 - 2) Maximum filament voltage (V)

Remarks : The maximum filament voltage shown here is the maximum of the filament voltage at the maximum filament current.

- k) X-ray radiation angle (°)
- l) Permanent filtration (mmCu, mmBe, mmAl)
 - 1) With respect to X-ray tube used mainly for therapy, it is expressed by the thickness of copper for nominal maximum tube voltage (nominal X-ray tube