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**Mono tank X-ray generators for
diagnostic use**

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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 the result of proposal for revision of Japanese Industrial Standard submitted by Japan Industries Association of Radiological Systems (JIRA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS Z 4711 : 1997** is replaced with this Standard.

This revision has been made based on **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* for the purposes of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

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Mono tank X-ray generators for diagnostic use

Introduction This Japanese Industrial Standard has been prepared based on the second edition of **IEC 60601-2-7** *Medical electrical equipment—Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators* published in 1998 with some modifications of the technical contents.

The portions given continuous sidelines or dotted underlines are the matters not stated in the original International Standard. A list of modifications with explanations is given in Annex 4 (informative). Terms in boldface are those specified in definitions of **JIS T 0601-1**, **JIS Z 4005**, **JIS Z 4701** or this Standard.

1 Scope This Standard specifies the **mono tank X-ray generators** for diagnostic use used for dental radiography, and mainly used for surgical radioscopy/radiography or for general radiography etc. as the movable type and portable type in the category of the **medical X-ray equipment** specified in **JIS Z 4701**.

NOTE : The International Standard corresponding to this Standard is 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 60601-2-7:1998 *Medical electrical equipment—Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators* (MOD)

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. If the indication of the year of coming into effect or publication is given to these referred standards, only the edition of the indicated year constitutes the provision of this Standard but the revision and amendment made thereafter do not apply. The normative references without the indication of the year of coming into effect apply only to the most recent editions (including amendments).

JIS C 8314 *Particular requirements for low-voltage cartridge fuses*

JIS C 8370 *Molded case circuit breakers (MCCB)*

JIS H 4000:1999 *Aluminium and aluminium alloy sheets, strips and plates*

JIS T 0601-1:1999 *Medical electrical equipment—Part 1: General requirements for safety*

NOTE : **IEC 60601-1:1988** *Medical electrical equipment—Part 1: General requirements for safety*, Amendment 1 (1993) and Amendment 2 (1995) are equivalent to the said standard.

JIS Z 4004 *Graphical symbols for medical radiological equipment*

NOTE : **IEC 60878**:1988 *Graphical symbols for electrical equipment in medical practice* is equivalent to the said standard.

JIS Z 4005:1991 *Medical radiology—Terminology*

NOTE : **IEC 60788**:1984 *Medical radiology—Terminology* is equivalent to the said standard.

JIS Z 4102:1994 *X-ray tube for medical use*

JIS Z 4701:1997 *General rules for medical X-ray equipment*

NOTE : **IEC 60601-1-3**:1994 *Medical electrical equipment—Part 1: General requirements for safety—3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment* is equivalent to the said standard.

JIS Z 4702:1999 *General requirements for high-voltage generators of medical X-ray apparatus*

NOTE : **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 4703:1995 *General requirements of mechanical units for medical X-ray equipment*

JIS Z 4704:2005 *X-ray tube assemblies for medical use*

NOTE : **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* is equivalent to the said standard.

JIS Z 4921:1994 *Measuring devices for X-ray tube voltage*

JIS Z 8601:1954 *Preferred numbers*

IEC 60522:1999 *Measurement of permanent filtration*

3 Definitions For the purpose of this Standard, the definitions given in **JIS T 0601-1**, **JIS Z 4005** and **JIS Z 4701**, and the following definitions apply.

3.1 one-peak X-ray generator an **X-ray generator** using **one-peak X-ray high voltage generator**

3.2 two-peak X-ray generator an **X-ray generator** using **two-peak X-ray high voltage generator**

3.3 pre-heating type a heating system with exclusive circuit of **X-ray tube** filament which can heat **X-ray tube** filament prior to high-voltage generation

3.4 simultaneous heating type a heating system in which high-voltage generation and **X-ray tube** filament heating are performed simultaneously by closing the primary circuit of **high-voltage generator**

3.5 inverter type X-ray generator an **X-ray generator** using inverter type **high-voltage generator** which can obtain the required high-voltage by inverting direct current power to alternative current power during irradiation of **X-ray**

3.6 X-ray generating assembly a part in which the voltage supplied from the controller is transformed into high voltage to be loaded to **X-ray tube**, and this electric energy is converted to X-ray energy

Variable **diaphragm** or irradiation cylinder and its support may be included.

3.7 irradiation time time interval for **inverter type X-ray generator** between the instant that the electric potential difference of a high-tension circuit 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 value of 75 % of the peak value

When the electric potential difference exists in the range of the electrical angle of 45° to 135° in the **pre-heating type one-peak X-ray generator** and **two-peak X-ray generator**, that time interval shall be included in the **irradiation time** as an effective pulse. See figure 3, figure 4 and figure 5.

3.8 nominal shortest irradiation time shortest irradiation time to satisfy the predetermined stability and make the substantial density uniform in the case of the **automatic exposure control**, which is generally a value longer than the shortest irradiation time of a timer

The **nominal shortest irradiation time** from the relation between the elapsed time of **irradiation time** and fluorescence or dose shall be as shown in figure 1.

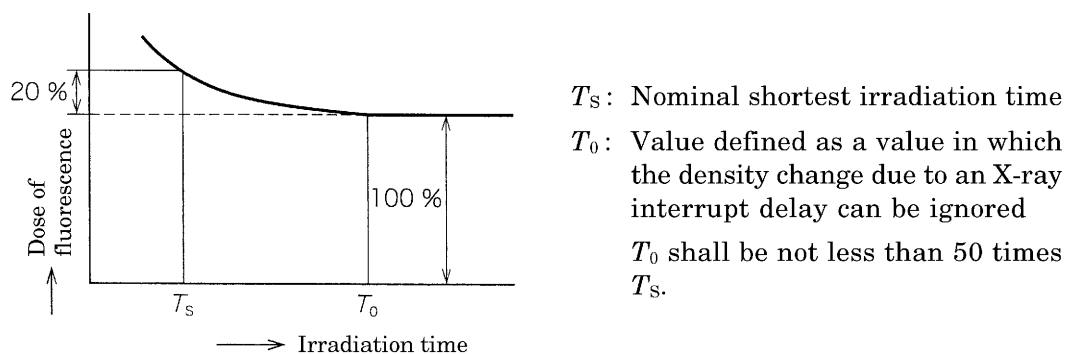


Figure 1 Nominal shortest irradiation time

3.9 nominal maximum power maximum power which can supply single **X-ray tube** load during the loading time specified in the **accompanying document** in the **X-ray generator**

This is the product of maximum **tube current** and **tube voltage** at 100 kV of **tube voltage** (a value nearest to 100 kV in the equipment which cannot be set to 100 kV) during the loading time of 0.1 s for the **inverter type X-ray generator** and transformer type **X-ray generator**. The **nominal maximum power** shall be expressed in kilowatt (kW) and obtained according to the following formula.

$$P = U \times I \times f \times 10^{-3} \dots\dots\dots (1)$$

where, P : **nominal maximum power** (kW)
 U : **tube voltage** (kV)
 I : **tube current** (mA)

f : factor depending on the waveform of **tube voltage** and is either of the following

- a) 0.74: **one-peak** and **two-peak X-ray generators**
- b) In the **inverter type X-ray generator**, the most suitable value from the waveform of **tube voltage** shall be selected from 0.74, 0.95, and 1.00, and the reason for selection shall be made clear.

NOTE : For the value of f , the following value shall be referred to.

$f = 1.00$ Percentage ripple $\leq 10 \%$

$f = 0.95$ $10 \% < \text{percentage ripple} \leq 25 \%$

$f = 0.74$ $25 \% < \text{percentage ripple}$

The percentage ripple of **tube voltage** shall be obtained according to the following formula.

$$\frac{U_{\max} - U_{\min}}{U_{\max}} \times 100 \dots\dots\dots (2)$$

where, $U_{\max}$: maximum value of **tube voltage** waveform in each period of power supply

$U_{\min}$: minimum value of **tube voltage** waveform in each period of power supply

4 Classification and type designation The **X-ray generator** shall be classified into two types, transformer type and inverter type as follows. The type designation shall be denoted by the combination of letters and numerals in accordance with the following order (see notes to table 1 and table 2).

- a) The **transformer type X-ray generator** shall include **one-peak X-ray generator** and **two-peak X-ray generator**. The standard type designations shall be as given in table 1.

**Table 1 Type designation of transformer type X-ray generator
(one-peak X-ray generator and two-peak X-ray generator)**

Type designation ⁽¹⁾	Usage	Nominal maximum tube voltage kV
MRF-70	For radioscopy and radiography	70
MRF-80		80
MRF-100		100
MRF-125		125
MR-60	For radiography	60
MR-70		70
MR-80		80
MR-100		100
MR-125		125
MR-60-S		60
MR-70-S		70
MR-80-S		80

Note ⁽¹⁾ The denotation method of type designations shall be as follows.

Example: MR -70 -S

S: **Simultaneous heating type**
 Without symbol: **Pre-heating type**
 Z: **Pre-heating type in two-peak X-ray generator**
 — **Tube voltage** [expressed in kilovolt (kV)]
 — MRF: For **radioscopy** and **radiography**
 — MR: Only for **radiography**

- b) The **inverter type X-ray generators** shall include transformer **inverter type X-ray generator** and stored energy **inverter type X-ray generator**. The standard type designation of transformer **inverter type X-ray generator** shall be as given in table 2. For the standard type designation of stored energy **inverter type X-ray generator**, table 2 shall be correspondingly applied.

**Table 2 Type designation of inverter type X-ray generator
(transformer inverter type X-ray generator)**

Type designation ⁽²⁾ ⁽³⁾	Usage	Nominal maximum tube voltage kV
MIRF-70	For radioscopy and radiography	70
MIRF-80		80
MIRF-100		100
MIRF-125		125
MIR-60	For radiography	60
MIR-70		70
MIR-80		80
MIR-100		100
MIR-125		125

Notes ⁽²⁾ The denotation method of type designation of transformer **inverter type X-ray generator** shall be as follows.

Example: MIRF -70
 └───┬───┘
 └───┘ **Tube voltage** [expressed in kilovolt (kV)]
 └───┘ MIRF: For **radioscopy** and **radiography**
 └───┘ MIR: Only for **radiography**

⁽³⁾ The denotation method of type designation of stored energy **inverter type X-ray generator** shall be as follows.

Example: MBIRF -70
 └───┬───┘
 └───┘ **Tube voltage** [expressed in kilovolt (kV)]
 └───┘ MBIRF: For **radioscopy** and **radiography** of battery
 stored energy **inverter type X-ray generator**
 └───┘ MBIR: Only for **radiography** of battery stored energy
inverter type X-ray generator

5 Ratings The ratings of **one-peak X-ray generator** and **two-peak X-ray generator** shall be as given in table 3 and of **inverter type X-ray generator** shall be as given in table 4. The test shall be performed in accordance with **10.2**.

Table 3 Ratings (One-peak X-ray generator and two-peak X-ray generator)

Type designation	Long-time ratings			Short-time ratings				Maximum apparent power kVA
	Maximum rated tube voltage kV	Maximum tube current at maximum rated tube voltage mA	Time min	Tube voltage				
				60, 70 kV	80 kV	100 kV	125 kV	
				Maximum tube current at each rated tube voltage mA				
MRF-70	70	4 max.	10 min.	10 to 30	—	—	—	3.0 max. ⁽⁴⁾
MRF-80	80				10 to 20			
MRF-100	100			10 to 40	10 to 30	10		
MRF-125	125			10 to 40	10 to 30	20	10	
MR-60	—	—	—	5 to 30	—	—	—	
MR-70								
MR-80					5 to 20			
MR-100				5 to 40	5 to 30	5 to 10		
MR-125				5 to 40	5 to 30	5 to 20	5 to 10	
MR-60-S	—	—	—	5 to 30	—	—	—	
MR-70-S								
MR-80-S					5 to 20			

Table 4 Ratings (Inverter type X-ray generator)

Type designation	Long-time ratings			Short-time ratings				Maximum apparent power kVA	
	Maximum rated tube voltage kV	Maximum tube current at maximum rated tube voltage mA	Time min	Tube voltage					
				60, 70 kV	80 kV	100 kV	125 kV		
				Maximum tube current at each rated tube voltage mA					
MIRF-70	70	4 max.	10 min.	5 to 25	—	—	—	3.0 max. ⁽⁴⁾	
MIRF-80	80				5 to 20	5 to 20			5 to 12.5
MIRF-100	100								
MIRF-125	125								
MIR-60	—	—	—	5 to 25	—	—	—		
MIR-70					5 to 20	5 to 16			
MIR-80									
MIR-100				5 to 40	5 to 30	5 to 16	5 to 12.5		
MIR-125									
MBIR-100									
MBIR-125									

Note ⁽⁴⁾ Those requiring the capacity of power supply exceeding 3.0 kVA shall be in accordance with clause 6 of JIS Z 4702.

- NOTES 1 The **mono tank X-ray generator** exceeding the apparent power of 3 kVA which is not described in table 3 and table 4 and the stored energy inverter type X-ray generator exceeding the short-time rating in table 4 shall be in accordance with the classification in 4 a) 1) and 2) and the rating in 5 a) of **JIS Z 4702** which are applied to their **high-voltage equipment**.
- 2 The long-time rating given in table 3 and table 4 is the rating in the **radioscopy** which uses the normal dose rate.

6 Environmental conditions and power supply

6.1 Environmental conditions The environmental conditions are as follows when not described in the instructions for use. Otherwise, these shall be in accordance with clause 10 of **JIS T 0601-1**.

Ambient temperature range: 10 °C to 40 °C

Relative humidity range: 30 % to 85 %

Atmospheric pressure range: 700 hPa to 1 060 hPa

6.2 Power supply The power supply shall be as given in table 5.

Table 5 Power supply

Number of phases	Frequency Hz	Nominal rated voltage V	Allowable voltage range at no load V	Apparent resistance of power supply Ω ⁽⁵⁾
1	50 or 60	100	90 to 110	R_1
		200	180 to 220	R_2

Note ⁽⁵⁾ **The apparent resistance of power supply** shall be $R_1 \leq 0.2 \Omega$, $R_2 \leq 0.8 \Omega$. However, in the case where the **power supply voltage** drop rate is not more than 10 % at the maximum value of short-time rated load, the resistance shall have a value at which the **power supply voltage** drop rate becomes 10 % at the condition of $R_1 \leq 0.5 \Omega$, $R_2 \leq 2.0 \Omega$, respectively. The power supply voltage drop rate shall be obtained by the following formula.

$$\frac{U_n - U_L}{U_L} \times 100 \% \dots\dots\dots (3)$$

where, U_n : power supply voltage at no load (V)

U_L : power supply voltage at short-time maximum rated load (V)

7 Performance

7.1 Tube voltage Errors on the setting value of **tube voltage** shall be within $\pm 10 \%$. The test shall be performed in accordance with 10.3.

7.2 Tube current The tolerance on the indicated value of **tube current** shall be within $\pm 20 \%$ of the rated value. The test shall be performed in accordance with 10.4.

7.3 Radiographic timer The **irradiation time** series of a radiographic timer shall consist of the preferred number of R10 series specified in **JIS Z 8601** and the adjustable range shall be as given in table 6. The tolerance on the setting value of **irradiation time** shall be within $\pm(10\% + 1 \text{ ms})$. The test shall be performed in accordance with **10.5**. However, the tolerance on the setting value of less than 0.2 s in the **one-peak X-ray generator** and less than 0.1 s in the **two-peak X-ray generator** shall be ± 1 pulse. For the **X-ray generator** used for the intraoral **X-ray equipment** for radiography, the **X-ray equipment** for **dental panoramic tomography** and the **X-ray equipment** for cephalometric radiography, the upper limit values and lower limit values of these may not be applied.

Table 6 Radiographic timer

Unit: s

Usage of X-ray generator	Lower limit value	Upper limit value
MRF MR	0.1 max. ⁽⁶⁾	5 ⁽⁶⁾
MIRF MIR		

Note ⁽⁶⁾ This upper limit value shall be 3.2 s or less and the ratio of the upper limit to the lower limit shall be 16 or more in the case of using a dental X-ray equipment with an intraoral **X-ray image receptor** for radiography (the dental X-ray film, dental imaging plate, etc. which are used by inserting into the oral cavity).

7.4 Tube current time product The tolerance on the setting value of **tube current time product** shall be within $\pm(10\% + 0.2 \text{ mAs})$. The test shall be performed in accordance with **10.6**.

7.5 Reproducibility of X-ray output As for the reproducibility of **X-ray output at irradiation**, the variation factor specified in **7 a) 5)** of **JIS Z 4702** shall be 0.05 or less under all the combinations of **X-ray conditions** within the range stated in the instructions for use.

7.6 Linearity of X-ray output at adjacent settings When the test is performed in accordance with **10.8**, the rate of **X-ray output** to the setting value of the product of the **tube current** and **irradiation time** or of the **tube current time product** at adjacent settings of the **tube current** and **irradiation time** or **tube current time product** shall satisfy the following formula.

$$\left| \frac{\overline{K}_1}{I_1 t_1} - \frac{\overline{K}_2}{I_2 t_2} \right| \leq 0.2 \frac{\frac{K_1}{I_1 t_1} + \frac{K_2}{I_2 t_2}}{2} \dots\dots\dots (4)$$

where, K_1, K_2 : mean value of **X-ray** output measured at adjacent setting value (mGy)

I_1, I_2 : adjacent set value of **tube current** (mA)

t_1, t_2 : adjacent set value of **radiographic time** (s)

However, for the **X-ray generator of tube current time product** control system, apply the formula (2) by assuming $I_1 t_1 = Q_1$, $I_2 t_2 = Q_2$, where, Q_1 and Q_2 denote **tube current time product** (mAs).

NOTE : The **X-ray** outputs of K_1 and K_2 are **air kerma** measured in air and those are denoted by unit of gray (Gy). 1 Gy in **air kerma** corresponds to 29.4 mC/kg (115 R).

7.7 Stability of X-ray output in automatic control system The stability of X-ray output in automatic control system shall be in accordance with 7.7) of **JIS Z 4702**.

8 Construction

8.1 Fundamental construction The components and assemblies shall be in accordance with clause 10 of **JIS T 0601-1**.

8.2 Adjustable range of tube voltage The adjustable range and adjustable steps of **tube voltage** in the **tube voltage** adjustable type among the standard **X-ray generators** type designation shall be as given in table 7. The setting value of **tube voltage** of the **X-ray generator** without the adjustable function of **tube voltage** shall be its rated value of **tube voltage**.

NOTE : The range of **tube voltage** of the **X-ray generator** used for the dental **X-ray equipment** shall be in accordance with 8.1.1 of **JIS Z 4701**.

Table 7 Adjustable range of tube voltage

Unit: kV

Type designation	Adjustable range of tube voltage			
	Long-time rating		Short-time rating	
	Adjustable range	Adjustable steps	Adjustable range	Adjustable steps
MRF-70	60 to 70	10 max.	40 to 70	10 max.
MRF-80	60 to 80		40 to 80	
MRF-100	60 to 100		40 to 100	15 max.
MRF-125	60 to 125		40 to 125	
MR-60	—	—	60	10 max.
MR-70			60 to 70	
MR-80			60 to 80	
MR-100			40 to 100	15 max.
MR-125			40 to 125	
MR-60-S	—	—	60	10 max.
MR-70-S			60 to 70	
MR-80-S			60 to 80	15 max.
MIRF-70	60 to 70	10 max.	40 to 70	10 max.
MIRF-80	60 to 80		40 to 80	
MIRF-100	60 to 100		40 to 100	15 max.
MIRF-125	60 to 125		40 to 125	
MIR-60	—	—	60	10 max.
MIR-70			60 to 70	
MIR-80			40 to 80	15 max.
MIR-100			40 to 100	
MIR-125			40 to 125	
MBIR-100	—	—	40 to 100	
MBIR-125			40 to 125	

8.3 Composition of X-ray generating assembly The X-ray generating assembly shall be composed of the combination of the components shown in table 8.