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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

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**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