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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 13797-2023

Replacing GB/T 13797-2009

General specifications for X-ray tube

医用X射线管通用技术条件

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1 Scope

GB/T 13797-2023 is the Chinese national standard on general specifications for x-ray tube, in the field of health care technology. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 17 March 2023 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 April 2024. Classification: ICS 11.040.50, CCS C43. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document defines the terms and definitions of medical X-ray tubes, and specifies the requirements and test methods for medical X-ray tubes. This document applies to medical X-ray tubes.

Note: This product, used as the ray source of medical X-ray equipment, is assembled in the sleeve (X-ray tube assembly) that uses oil as the insulating and cooling medium; it is used for supporting medical X-ray equipment.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the version corresponding to that date is applicable to this document; for undated references, the latest version (including all amendments) is applicable to this document.

GB/T 1804, General tolerances - Tolerances for linear and angular dimensions without individual tolerance indications

GB/T 2423.1-2008, Environmental testing for electric and electronic products - Part 2: Test methods - Tests A: Cold

GB/T 2423.2-2008, Environmental testing for electric and electronic products - Part 2: Test methods - Tests B: Dry heat

GB/T 2423.3-2016, Environmental testing - Part 2: Testing method - Test Cab: Damp heat, steady state

GB/T 4798.2-2021, Classification of environmental conditions - Classification of groups of environmental parameters and their severities - Part 2: Transportation and handling

GB 9706.1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

GB 9706.228, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

GB/T 10149, Terminology and symbol for medical X-ray equipment The overall dimensions of medical X-ray tubes shall be given by the manufacturer in the accompanying documents as diagrams, and the unmarked tolerances of the overall dimensions shall comply with the provisions of level V in GB/T 1804.

4.2.2 Electrode connection The electrode connection diagram of medical X-ray tubes shall be given by the manufacturer in the accompanying documents.

4.3 Appearance and structure

4.3.1 Shell The following requirements shall be met:

a) There shall be no opaque sand spots on the glass shell of the X-ray tube; the surface of the shell of other materials shall be smooth and clean without damage;

b) There shall be no defects such as gas lines, bubbles and scratches in the X-ray window area of the glass bulb; there shall be no defects such as particles, cracks, scratches, grooves, and burrs in the X-ray window area of other materials.

4.3.2 Electrode surface There shall be no damage affecting the performance of the

electrode surface in the X- ray tube, and there shall be no foreign matter melted on the actual focal plane.

4.3.3 Foreign objects in the tube There shall be no foreign objects in the X-ray tube that affect the normal work, such as movable metal particles, fibrous foreign objects.

4.4 Photoelectric performance

4.4.1 Nominal X-ray tube voltage The nominal tube voltage of medical X-ray tubes shall be given by the manufacturer in the accompanying documents, which shall meet the requirements of YY/T 0064-2016.

4.4.2 Overvoltage The X-ray tube shall be able to withstand

1.1 times the nominal X-ray tube voltage for 3 minutes, during which there shall be no abnormal discharge phenomena, such as flashover and breakdown. If the nominal X-ray tube voltage of the X-ray tube in the fluoroscopy mode exceeds 80% of the nominal X-ray tube voltage in the photography mode, the X-ray tube shall also be able to withstand the nominal X-ray tube voltage of

1.1 times the fluoroscopy mode, for 15 min, during which there shall be no abnormal discharge phenomenon, such as flashover and breakdown.

4.4.3 Cathode emission characteristics The cathode emission characteristics of medical X-ray tubes shall be given by the manufacturer in the accompanying documents, which shall comply with the requirements of YY/T 0064-2016.

4.4.4 Input power

4.4.4.1 Nominal anode input power The nominal anode input power of the medical X-ray tube shall be given by the manufacturer in the accompanying documents, which shall comply with the requirements of YY/T 0064-2016.

4.4.4.2 Nominal photographic anode input power The nominal photographic anode input power of the medical X-ray tube shall be given by the manufacturer in the accompanying documents, which shall comply with the requirements of YY/T 0064-2016.

4.4.4.3 Nominal CT anode input power The nominal CT anode input power of the medical X-ray tube shall be given by the manufacturer in the accompanying documents, which shall comply with the requirements of YY/T 0064-2016.

4.4.4.4 CT scan power index (CTSPI) The nominal CT scan power index (CTSPI) of the medical X-ray tube shall be given by the manufacturer in the accompanying documents, which shall comply with the requirements of YY/T 0064-2016.

4.4.4.5 Continuous anode input power The continuous anode input power of the medical X-ray tube shall be given by the manufacturer in the accompanying documents, which shall

comply with the requirements of YY/T 0064-2016.

Note: As the continuous anode input power is affected by the external environment, the manufacturer can give the boundary conditions of the continuous anode input power, such as oil temperature, cooling conditions.

4.4.4.6 Single rated load The single rated load of the medical X-ray tube shall be given by the manufacturer in the accompanying documents. The X-ray tube shall be subjected to the vibration test specified in 5.5.4. After the test, there shall be no mechanical damage by visual inspection. It shall work normally at the nominal X-ray tube voltage.

4.6 Expected service life The manufacturer of the medical X-ray tube shall give the expected service life in the accompanying documents, and shall provide the corresponding verification documents. See Appendix A for more information on expected service life. The expected service life shall be expressed in years or months or loading times or kilowatt-seconds (kW·s), and that for CT tube can be expressed in scan seconds (ss) or scan times. If the expected service life is expressed in years or months, the basis shall be given in the accompanying documents.

4.7 Accompanying documents

4.7.1 General Accompanying documents may be provided together with the X-ray tube; alternatively, they may be incorporated into the accompanying documents for any X-ray tube assembly equipped with the X-ray tube. Where applicable, accompanying documents shall include the following: -- name or trademark and contact information of the manufacturer for reference by the responsible party; -- model or type reference number.

4.7.2 Instruction manual The instruction manual for the X-ray tube shall state its intended use. The instruction manual shall specify the following data:

a) target material for determining the radiant energy spectrum;

b) target angle;

c) focus nominal value;

d) permanent filtration determined according to

YY/T 0062, or thickness and chemical symbols of relevant materials;

e) nominal X-ray tube voltage specified in YY/T 0064-2016;

f) cathode emission characteristics specified in YY/T 0064-2016;

g) case voltage specified in

YY/T 0064-2016, if applicable;

h) case current specified in