

ICS 11.040.50
CCS C 43

YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0010-1990

**Particular specifications for dental intra-oral X-ray equipment
(English Translation)**

Issued on: January 1, 2002

Implemented on: June 1, 2021

Issued by: the National Medical Products Administration

Table of Contents

Foreword
1 Scope
2 Normative references
3 Terms and definitions
4 System configuration
5 Requirements
5.1 Working conditions
5.2 Electric power
5.3 Loading factors and control
5.4 Imaging performance

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard replaces YY/T 0010-2008 "Specific technical conditions for dental X-ray machines." Compared with YY/T 0010-2008, the main technical parameters of this standard are as follows.

---Modified the standard name, and changed the "special technical requirements for oral X-ray machines" to "special technical specifications for intraoral imaging dental X-ray machines" Pieces".

---Modified the scope (see Chapter 1, Chapter 1 in the 2008 edition);

---Modified terms and definitions (see Chapter 3, Chapter 3 in the 2008 edition);

---Modified the classification (see 4.1, 4.1 in the 2008 edition);

---Modified the composition (see 4.2, 4.2 in the 2008 edition);

---Modified the adjustment range requirements of the X-ray tube voltage [see 5.3.1a), 5.3.1a) in the 2008 edition];

---Modified the loading time requirements (see 5.3.3, 5.3.3 in the 2008 edition);

---Modified the adjustment range requirements of the current time product [see 5.3.4a), 5.3.4a) in the 2008 edition];

---Modified the limit of the distance from the focus to the skin (see 5.4.2, 5.4.2 in the 2008 edition);

---The relevant content of the oral and maxillofacial panoramic X-ray machine in the original standard has been deleted (see 4.1, 4.2, 5.3, 5.4, and 5.4 in the 2008 edition) 5.5);

---Added relevant requirements for handheld dental X-ray machines (see 5.3.6);

---Increase the requirements for line-pair resolution, low-contrast resolution, and image uniformity for products with electronic X-ray image receivers and test methods (see 5.4.3, 5.4.4, 5.4.5 and 6.4.3, 6.4.4, 6.4.5);

--- Added Appendix A.

1 Scope

This standard specifies the terms and definitions, system composition, requirements and test methods of dental X-ray machines for intraoral imaging (hereinafter referred to as dental machines).

This standard applies to X-ray machines that use intraoral X-ray image receivers to take X-ray pictures of teeth.

This standard does not apply to X-ray machines that use external X-ray image receivers for imaging.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article Pieces. For undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 9706.1 Medical electrical equipment Part 1: General requirements for safety GB 9706.3-2000 Medical electrical equipment Part 2: Special requirements for the safety of high-voltage generators for diagnostic X-ray generators GB 9706.11 Medical electrical equipment Part 2: Special requirements for the safety of medical diagnostic X-ray source components and X-ray tube components GB 9706.12 Medical electrical equipment Part 1: General requirements for safety 3.Parallel standard diagnostic X-ray equipment radiation protection General requirements GB 9706.14 Medical electrical equipment Part 2: Special requirements for the safety of auxiliary equipment of X-ray equipment GB 9706.15 Medical Electrical Equipment Part 1: General Requirements for Safety 1.Collateral standard. safety requirements for medical electrical systems GB/T 19042.4-2005 Evaluation and routine test of medical imaging department Part 3-4.Imaging performance of dental X-ray equipment Acceptance test YY 0505 Medical Electrical Equipment Part 1-2.General Safety Requirements Collateral Standard. Electromagnetic Compatibility Requirements and Tests YY/T 0291 Environmental requirements and test methods for medical X-ray equipment

3 Terms and definitions

GB 9706.1, GB 9706.3-2000, GB 9706.11, GB 9706.12, GB 9706.14, GB 9706.15, GB/T 19042.4-2005, the terms and definitions defined in YY 0505, YY/T 0291 and the following apply to this document.

It is related to dental X-ray imaging, in which the X-ray image receiver is entirely or partly located in the oral cavity.

An X-ray machine that uses an intraoral X-ray image receiver to take X-ray pictures of teeth.

X-ray image receiver using electronic conversion method.

The movable mechanism connected with the X-ray tube head in the dental X-ray machine.

X-ray tube assembly including high-voltage transformer assembly.

4 System configuration

4.1

The classifications are as follows according to the structure, installation and use mode.

- a) Fixed;
- b) Mobile;
- c) Portable;
- d) Handheld.

4.2

The composition of the dental X-ray machine is shown in Figure 1.

Dental X-ray machines generally consist of X-ray generators, telescopic arms and other accessories, and may be equipped with X-ray image receivers.

equipment.

Figure 1 The composition of the dental X-ray machine

5.1.1 Environmental conditions

Unless otherwise specified, the working environment conditions of the dental machine should meet.

- a) Ambient temperature. 10°C~40°C;
- b) Relative humidity. 30%~75%;
- c) Atmospheric pressure. 700hPa~1060hPa.

5.1.2 Power supply conditions

The working power supply conditions of the dental machine should meet.

- a) The power supply voltage and the number of phases specified by the manufacturer, and the fluctuation of the grid voltage should not exceed $\pm 10\%$ of the nominal value;
- b) Power frequency. 50 Hz $\pm$ 1 Hz;
- c) The power supply resistance specified by the manufacturer [The applicable power supply resistance should not be less than 10.2.2a in GB 9706.3-2000) Table 101 Specified value];
- d) The power supply capacity specified by the manufacturer.

5.2.1 Maximum output power

The manufacturer shall specify the corresponding combination of X-ray tube voltage and X-ray tube current that results in the maximum output electric power.

5.2.2 Nominal electric power

The manufacturer shall stipulate that when the loading time is 0.1s and the X-ray tube voltage is 100kV, the dental unit can provide the unit of kW the maximum constant electric power output is given as the nominal electric power. If this value cannot be pre-selected, the X-ray tube closest to 100kV can be used the voltage value and the closest loading time value, but should not be shorter than 0.1s.

The nominal electric power should be given together with the combination of X-ray tube voltage and X-ray tube current and loading time.

5.3.1 X-ray tube voltage

The voltage of the X-ray tube should meet the following requirements.

- a) The manufacturer shall specify the adjustment range and method of the X-ray tube voltage, and shall comply with the following requirements. tube voltage can be fixed the tube voltage can be adjusted in two ways, the tube voltage should not be less than 60kV; if the step adjustment is adopted, the adjacent tube voltage increase should not be More than 5kV;
- b) The manufacturer shall specify the deviation of the X-ray tube voltage value, but at least it shall meet the requirements of 50.103.1 in GB 9706.3-2000.

5.3.2 X-ray tube current

X-ray tube current should meet the following requirements.

- a) The manufacturer shall specify the adjustment range and adjustment method of the X-ray