

ICS 11.040.50

C 43



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

**中华人民共和国医药行业标准**

YY/T 0310-2015

Replace YY/T 0310-2005

---

**General specifications for X-ray equipment for  
computed tomography**

**X 射线计算机体层摄影设备通用技术条件**

**Issued on March 02, 2015**

**Implemented on January 01, 2016**

---

**Issued by China Food and Drug Administration**

## Contents

<b>Foreword</b> .....	<b>I</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative References</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Classification and composition</b> .....	<b>2</b>
<b>5 Requirements</b> .....	<b>3</b>
<b>6 Test method</b> .....	<b>10</b>

## Foreword

This standard is drafted according to the rules specified by GB/T 1.1-2009.

This standard replaces YY 0310-2005 *General specifications for X-ray equipment for computed tomography*.

Compared with YY 0310-2005, this standard has made main technological revisions as follows:

- Revise the description of applicable scope, add to which CT scanning device provides image data for radiotherapy treatment planning;
- Add two standards, normative references YY 0505 and YY/T 0708;
- Adjust environmental conditions in requirements to conditions required by GB 9706.1;
- Add requirements of rotational speed of scanner;
- Modify “scanning time” to “exposure time”;
- Delete indicating instrument (5.5.5 in Version 2005);
- Add requirements of radiation treatment planning(RTP) and test methods.

This standard is proposed by China Food and Drug Administration.

This standard is under the jurisdiction of Technical Subcommittee of Medical X-ray Equipment and Tools of National Technical Committee of Medical Electric Appliances Standardization (SAC/TC 10/SC 1).

Drafting organizations of this standard: Liaoning Institute of Medical Device Testing, HangWei GE Medical System Co., Ltd.

Chief drafting staff: Wang Jianjun, Hao Suli, Mou Li, Han Qiang, Wang Shoumin.

The historical version replaced by this standard is as follows:

- YY 0310-1998, YY 0310-2005.

## **General specifications for X-ray equipment for computed tomography**

### **1 Scope**

This standard specifies terms and definitions, classification, composition, requirements and test methods of X-ray equipment for computed tomography ( hereafter referred to as CT scanning device).

This standard applies to CT scanning devices, including the CT scanning device provides image data for radiotherapy treatment planning.

### **2 Normative References**

The following quoted documents for the application of this document is essential. For dated reference documents, only the dated edition applies to this document. For undated reference documents, the latest edition (including all amendments) applies to this document.

GB 9706.1 Medical electrical equipment--Part 1:General requirements for safety

GB 9706.11 Medical electrical equipment-Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis

GB 9706.12 Medical electrical equipment-Part 1: General requirements for safety  
3.collateral STANDARD: General requirements for radiation protection in diagnostic X-ray equipment

GB 9706.14 Medical electrical equipment-Part 2: Particular requirements for the safety of associated 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 9706.18 Medical electrical equipment - Part 2:Particular requirements for the safety of X-ray equipment for computed tomography

GB/T 10149 Terminology and symbol for medical X-ray equipment

---

---

**完整版本请在线下单/Order Checks Online for Full version**

**联系我们/or Contact:**

TEL: 400-678-1309

QQ: 19315219 | Skype: Lancarver

Email : [info@lancarver.com](mailto:info@lancarver.com)

<http://www.lancarver.com>

---

---

**线下付款方式 :**

**I. 对公账户 :**

**单位名称 :** 北京文心雕语翻译有限公司

**开户行 :** 中国工商银行北京学清路支行

**账 号 :** 0200 1486 0900 0006 131

---

---

**II. 支付宝账户 : [info@lancarver.com](mailto:info@lancarver.com)**

**III. Paypal: [info@lancarver.com](mailto:info@lancarver.com)**

---

---

注: 付款成功后, 请预留电邮, 完整版本将在一个工作日内通过电子 PDF 或 Word 形式发送至您的预留邮箱, 如需索取发票, 下单成功后的三个工作日内安排开具并寄出, 预祝合作愉快!

**NOTE** All documents on the store are in electronic Adobe Acrobat PDF format, there is not sell or ship documents in hard copy. Mail the order and payment information to [info@lancarver.com](mailto:info@lancarver.com), you will shortly receive an e-mail confirming your order.

---

