

PROFESSIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国医药行业标准

YY 0831.1-2011

Stereotactic radiotherapy system with gamma beam—Part 1:Multi-source stereotactic radiotherapy system with gamma beam for head lesion

γ 射束立体定向放射治疗系统

第 1 部分: 头部多源 γ 射束立体定向放射治疗系统

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Foreword

Full text of this part is mandatory.

YY 0831 consists of two parts are as follows:

- Part 1:Multi-source stereotactic radiotherapy system with gamma beam for head lesion;
- Part 2:Multi-source stereotactic radiotherapy system with gamma beam for body lesion;

This part of YY 0831 is part 1.

This part is drafted according to the rules specified in GB/T 1.1-2009

Please note that some contents in this document may involve in the patent. The issuing authority of this document will not bear the responsibilities of these patents.

The part is proposed by China Food and Drug Administration.

The part is under the jurisdiction of National Standardization Technical Committee of Medical Appliances Radiotherapy and Technical Committee of Nuclear Medicine and Radiation Dosimetry Equipment (SAC/TC10/SC3).

The part is mainly drafted by: Beijing Institute of Medical Device Testing, Shenzhen Haibo Technology Co., Ltd, Medical Science & Technology Development (Shenzhen) Co., Ltd (MASEP), Shenzhen Shengai Medical Technology Development Co., Ltd and Shenzhen Zunrui Technology Co., Ltd.

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Stereotactic radiotherapy system with gamma beam—Part 1:Multi-source stereotactic radiotherapy system with gamma beam for head lesion

1 Scope

This section of YY 0831 provides the scope, terms, definitions, requirements and test methods of the multi-source stereotactic radiotherapy system with gamma beam for head lesion.

This section applies to the multi-source stereotactic radiotherapy system with gamma beam for head lesion (hereinafter referred to as the system), the system simultaneously uses multiple ⁶⁰Co sealed radioactive sources (which may be dynamic or static) to conduct beaming to the lesion are of the head.

2 Normative references

The articles contained in the following documents have become this document when they are quoted herein. For the dated documents so quoted, all the modifications (Including all corrections) or revisions made thereafter shall be applicable to this document.

GB 9706.1-2007 Medical electrical equipment—Part 1: General requirements for safety
GB 9706.15-2008 Medical electrical equipment - Part 1: General requirements for safety -

1. Collateral standard: Safety requirements for medical electrical systems

GB 9706.17-2009 Medical electrical equipment - Part 2: Particular requirements for the safety of gamma beam therapy equipment

GB/T 17857-1999Medical radiology--Terminology (Equipment for radiotherapy, nuclear medicine and radiation dosimetry)

GB/T 18987-2003Radiotherapy equipment—Coordinates, movements and scales

YY 0637-2012 Medical electrical equipment—Requirements for the safety of radiotherapy
treatment planning systems

3 Terms and definitions

Those defined in GB/T 17857-1999 and the following terms and definitions apply to this



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