

ICS 11.040.55

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

YY/T 1719-2023

**General requirements of positron emission tomography and
magnetic resonance imaging equipment**

正电子发射断层成像及磁共振成像设备通用技术要求

Issued on: January 13, 2023

Implemented on: January 15, 2026

Issued by: National Medical Products Administration

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1. Structure and Drafting Rules for Standardization Documents" drafting. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is sponsored by the National Medical Electrical Appliance Standardization Technical Committee Medical Electronic Instrument Standardization Sub-Technical Committee (SAC/TC10/SC5) Focus on. This document is drafted by: Shanghai United Imaging Medical Technology Co., Ltd., Shanghai Medical Device Inspection and Research Institute, Shanghai Medical Devices Cosmetics Review and Inspection Center. The main drafters of this document. Pang Hexi, Hu Sheng, Liu Xin, Hu Lingzhi, Shen Zhenhua, Yang Yu, Yang Yiqiang.

The properties of the positron emission tomography part (hereinafter referred to as the PET part) in the positron emission tomography and magnetic resonance imaging system The reference standard for performance and test methods is GB/T 18988.1-2013, performance and test of magnetic resonance imaging part (hereinafter referred to as MR part) The reference standard of the method is YY/T 1840-2023. For the PET part, the two methods in the main text of GB/T 18988.1-2013 and Appendix NB have different test requirements and test methods. There are differences in the phantoms, test conditions, test locations, and calculation methods used, so the two methods of detection items cannot be compared with each other. For comparison, it is recommended that users of the standard refer to either method in its entirety and should not be cross-used. Positron emission tomography and magnetic resonance imaging equipment General Technical Requirements

1 Scope

YY/T 1719 covers the combined PET/MR scanner, the hybrid that acquires positron emission tomography and magnetic resonance images of the same anatomy. Combining the two raises problems neither has alone: the PET detectors have to work inside a strong magnetic field, the MR has to tolerate the detector hardware inside its bore, and the

attenuation correction that PET normally derives from CT has to be derived from MR instead. This document sets the general requirements such a system has to meet and how they are demonstrated. PET/MR is a small but strategically important segment in Chinese oncology and neurology imaging. The 2023 edition takes effect in January 2026. For a manufacturer, this is the text that governs the combined system, over and above the standards for each modality separately.

YY/T 0482 Determination of main image quality parameters of medical magnetic resonance imaging equipment

YY/T 1840-2023 General technical requirements for medical magnetic resonance imaging equipment

YY 9706.233 Medical electrical equipment Part 2-

33.Particular requirements for basic safety and essential performance of magnetic resonance equipment for medical diagnosis

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 9706.1 Medical Electrical Equipment Part

3 Terms and Definitions

Defined by GB/T 17857, GB/T 18988.1-2013, YY/T 0482, YY/T 1840-2023 and the following terms and definitions apply to this document.

3.1 The PET and MR parts sequentially scan and image the same imaging area to achieve image registration.

3.2 The PET and MR parts simultaneously scan and image the same imaging area to achieve image registration.

3.3 Split PET/MR separatedPET/MR The PET detector center does not coincide with the MR isocenter.

3.4 Integrated PET/MR integratedPET/MR The PET detector center coincides with the MR isocenter.