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

YY/T 1894-2023

**Verification method for reliability index of medical magnetic
resonance equipment**

医用磁共振设备可靠性指标验证方法

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents" Drafting. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is sponsored by the National Medical Electrical Appliances Standardization Technical Committee Medical Electronic Instruments Standardization Sub-Technical Committee (SAC/TC10/SC5) Return to home. This document was drafted by: Shanghai Medical Device Inspection and Research Institute, Siemens (Shenzhen) Magnetic Resonance Co., Ltd., Shanghai United Imaging Medical Technology Co., Ltd., Hangwei General Electric Medical Systems Co., Ltd., and Philips (China) Investment Co., Ltd. The main drafters of this document. Yu Hongyi, Wang Jun, Jia Dongfang, Wang Kun, Chen Dayu, Hu Sheng, Yang Yu, Xu Luqin, Xing Xiaocong, and Ma Gang. Verification method for reliability index of medical magnetic resonance equipment

1 Scope

YY/T 1894 sets out how the reliability figures quoted for a medical MRI system are verified. An MRI scanner is among the most expensive assets a Chinese hospital buys and among the most disruptive to lose: a day of downtime is a day of cancelled examinations, and reliability claims are a real part of the purchasing decision. This document specifies how indices such as mean time between failures and availability are defined, what counts as a failure, over what period and under what conditions the observation is made, and how the resulting figure is validated. Without a common method the numbers in a tender are not comparable. For a manufacturer selling MRI into China this is the text a reliability claim has to be substantiated under, and for a hospital it is the basis on which a service contract can be written.

This document describes a method for verification of reliability indicators for medical

magnetic resonance equipment. This document applies to medical magnetic resonance equipment. This document does not apply to the software portion of medical magnetic resonance equipment.

2 Normative reference documents

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

YY/T 1837 General requirements for reliability of medical electrical equipment

3 Terms and definitions

The terms and definitions defined in YY/T 1837 apply to this document.

4 General principles

4.1 Goals of reliability index verification of medical magnetic resonance equipment Verify whether the magnetic resonance equipment meets the established reliability requirements by using methods such as reliability data analysis, reliability testing, and reliability prediction. Requirements for quantitative indicators. The goal of carrying out the verification of reliability indicators of medical magnetic resonance equipment is to analyze the basic functions and reliability of medical magnetic resonance equipment. Analyze, determine the quantitative reliability requirements of medical magnetic resonance, and be able to evaluate the lifespan and expected mean time between failures of medical magnetic resonance components and complete machines.

4.2 Basic principles for verification of reliability indicators of medical magnetic resonance equipment The basic principles are as follows:

---Due to the characteristics of the complete medical magnetic resonance machine, such as its large size, many components and uneven distribution, strong magnetic field, and ultra-low temperature, it is currently impossible to inspect the complete machine. Conduct effective accelerated life tests so that the reliability indicators of the entire machine can be assigned to each key component;

---When determining the fault of each key component, it should be based on whether it affects the basic functions of the entire system. For example, the ambient light is not in contact. It is faulty and cannot emit light normally. Such faults should not be regarded as a criterion for complete machine failure;

---For the verification of reliability indicators of components, for mature and improved

products, based on the components or technologies shared by the products before improvement, adopt Use reliability data for analysis and statistics; for newly developed products, life and accelerated life test methods can be used. verify.

4.3 Principles for evaluation of reliability index verification results of medical magnetic resonance equipment A comprehensive assessment of the verification of reliability indicators of medical magnetic resonance equipment includes the following aspects.