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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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Rail systems for supporting medical equipment

用于支撑医疗设备的轨道系统

(English Translation)

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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.

This document is modified to adopt ISO 19054:2005 "Track systems for supporting medical devices".

The technical differences between this document and ISO 19054:2005, and the reasons therefor, are as follows.

---ISO 4135 (see Chapter 3) has been replaced with the normatively referenced GB/T 4999 to adapt to my country's technical conditions;

---The terms "commissioning," "track end caps," and "single failure condition" in the "Terms and Definitions" chapter of ISO 19054:2005 have been removed to adapt to Chinese standards.

Technical conditions;

---ISO 14971 (see 4.1) has been replaced with the normatively referenced GB/T 42062 to adapt to my country's technical conditions;

---The phrase "if required by national or regional regulations" (see 4.4) has been removed to accommodate my country's technical conditions;

---ISO 1302 (see 5.2.5) has been replaced with the normatively referenced GB/T 131 to adapt to my country's technical conditions;

---ISO 6506-1 (see 5.2.6) has been replaced with the normatively referenced GB/T 231.1 to adapt to my country's technical conditions;

---EN980 (see 6.1) has been replaced with YY/T 0466.1 (normative reference) to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

---Incorporating content from ISO 19054:2005/AMD1.2016, the relevant clauses are indicated by a vertical double line in the outer margin.

((I)) has been marked to adapt to my country's technological conditions;

---Index number 12 and a note have been added to Figure 1;

---Some clauses have had their asterisks (*) removed, and notes have been added (see 4.2, 4.3.1, 5.2.6, 5.9);

---Appendix C adds information on China's electrical installation requirements.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Anesthesia and Respiratory Equipment (SAC/TC116).

Introduction

This document specifies the basic requirements and dimensions for track systems used to support medical equipment. The track system consists of multiple components that can be assembled into different configurations.

It consists of components.

The track system specified in this document enables the placement of medical equipment (such as flow meters, suction devices, and lights) next to the patient.

It can be installed in different locations in medical facilities, ambulances, and other transport vehicles, and can also be installed on different equipment (such as medical supply devices, hoists, etc.).

On the tower, trolley, bed, ventilator and anesthesia workstation.

Medical devices can be directly attached to the rail using a rail clamp or other components of the dimensions specified in this document.

The document specifies that the track dimensions are compatible.

An insufficiently strong track system may cause the medical equipment attached to it to become unstable or even fall, thus posing a danger.

The track system needs to be installed on different types of load-bearing structures, such as solid concrete walls, thin gypsum board partitions, or medical facilities.

Coverings are provided. Patients carrying medical equipment are frequently transferred to or moved within medical facilities, requiring track systems at different locations.

A lack of standardization can lead to dangerous situations when patients are moved from one location to another.

In medical settings, track-based medical devices are quite common. The track systems specified in this document do not include X-ray imaging equipment.

The sliding rail structure and suspension brackets used in examination beds for large medical equipment such as radiotherapy equipment, nuclear medicine and magnetic resonance imaging equipment this does not include trackless conveyor systems, the requirements for which are specified by relevant standards.

Appendix A provides a typical form of orbital system certification.

Appendix B contains explanations of the basis for some of the requirements in this document. It provides further context for the reasoning leading to the requirements and recommendations contained in this document.

More insights. Understanding the reasons behind these requirements will not only help in the correct application of this document, but also help expedite subsequent revisions.

Track system for supporting medical equipment

1 Scope

This document specifies the basic requirements for track systems used to support medical equipment, enabling the transfer of medical equipment from one track system to another.

A track system. The specifications of the track system include dimensions, strength, and information provided by the manufacturer.

This document applies to rail systems intended for horizontal installation. This document does not specify the structures the rail system can connect to or the medical equipment it can support.

Backup type.

This document does not apply to overhead track systems that support curtains and infusion devices.

Note 1: Some medical devices can be connected to the track in ways outside the scope of this document.

Note 2: Specific documentation is expected to be prepared to cover applications where the orbital systems specified in this document are not applicable.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

ISO 1302:2002, IDT

GB/T 231.1 Metallic materials - Brinell hardness test - Part 1: Test methods (GB/T 231.1-2018, ISO 6506-1) 2014, MOD) GB/T 4999 Terminology for Anesthesia and Respiratory Equipment (GB/T 4999-2003, ISO 4135:2001, IDT) GB/T 42062 Application of