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PEOPLE'S REPUBLIC OF CHINA**

GB/T 44665-2024

**General requirements for upper and lower limb motor function
rehabilitation equipment with assessment and training**

上下肢运动功能评估与训练设备通用要求

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Table of Contents

1 Scope	1
2 Normative references	1
3 Terms and Definitions	1
4 Categories	2
4.1 Classification by user	2
4.2 Classification by training method	2
5 Requirement	2
5.1 Appearance	2
5.2 Structure	2
5.3 Software	2
5.4 Motor function assessment and analysis	3
5.5 Rehabilitation training function	5
5.6 Working noise	6
5.7 Security Protection	6
5.8 Additional functions	7
5.9 Electrical safety	7
5.10 Electromagnetic compatibility	7
6 Test methods	7
6.1 Test conditions	7
6.2 Appearance Inspection	7
6.3 Structural inspection	7
6.4 Software Verification	7
6.5 Motor function assessment and analysis test	7
6.6 Rehabilitation training function test	7
6.7 Working noise test	8
6.8 Safety protection test	8
6.9 Additional functional inspection	8
6.10 Electrical safety test	9
6.11 Electromagnetic compatibility test	9
7 Labels, packaging, instructions for use	9
7.1 Signs	9
7.2 Packaging	9

Foreword

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

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1 Scope

GB/T 44665-2024 sets the general requirements for equipment that both assesses and trains upper and lower limb motor function - the robotic and mechanised trainers used after stroke and spinal injury. Combining assessment with training is what distinguishes this class of device: the machine measures range, strength, smoothness and assistance required while it works, and adjusts the training on that basis, which makes the validity of its measurements a clinical matter and not only a metrological one. The standard sets the categories, by user and by training method, then the requirements on appearance, structure, software, the motor function assessment and analysis, the rehabilitation training

function, working noise, safety protection, additional functions and electrical safety, together with the corresponding test methods, the inspection rules and the marking, packaging, transport and storage provisions. It takes effect on 1 January 2025.

This document provides the classification of upper and lower limb motor function assessment and training equipment, and specifies the upper and lower limb motor function assessment and training equipment Requirements, marking, packaging, instructions for use, and the corresponding test methods are described. This document is applicable to equipment for assessing and training upper and/or lower limb muscle strength, muscle tension, and joint range of motion for people with limb dysfunction.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 191 Pictorial markings for packaging, storage and transportation

GB 9706.1-2020 Medical electrical equipment Part

3 Terms and definitions

The terms and definitions defined in GB 9706.1-2020, GB 24436, YY/T 1626-2019 and the following apply to this document.

3.1 muscle strength The maximum voluntary contraction capacity of skeletal muscle.

3.2 Isometric muscle The strength of a muscle during isometric contraction (3.1).

Note. Isometric contraction, also known as static contraction, refers to a form of contraction in which the muscle tension increases without shortening its length.

3.3 isotonicmuscle The strength of a muscle during isotonic contraction (3.1).

Note. Isometric contraction is also called concentric contraction or dynamic contraction, which refers to the contraction form in which the muscle overcomes external force and shortens in length (the starting and ending points approach each other).

3.4 isokinetic muscle The strength of a muscle when it contracts isokinetically (3.1).