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**Rehabilitation robot for upper limb training - Requirements and
test methods**

上肢康复训练机器人 要求和试验方法

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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 of Standardization Documents" drafted: Please note that some content of this document may be patented: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by the Ministry of Civil Affairs of the People's Republic of China: This document is under the jurisdiction of the National Technical Committee on Standardization of Rehabilitation and Special Equipment for Persons with Disabilities (SAC/TC148): This document was drafted by: National Research Center for Rehabilitation Aids, Shanghai Zhuodao Medical Technology Co., Ltd., Anyang Shenfang Rehabilitation Robot Co., Ltd: Company, Shanghai University of Science and Technology: The main drafters of this document: Lan Zhi, Jian Zhuo, Yu Hongliu, Fu Fengsheng, Liu Junling, Li Hongliang, Wang Li, Wang Qiang, Wang Daoyu, Wang Duojin, Meng Qiaoling:

The upper limb rehabilitation training robot can automatically perform rehabilitation training and treatment tasks, thus playing an important role in the rehabilitation process: with tradition Compared with the training methods, the sports training involving robots has several obvious advantages: good repeatability, precise control, objective, predictable Quantitative evaluation standards, etc., can provide high-intensity, task-oriented training, which is very effective for the user's sports rehabilitation training: The synchronization of sensory and motor information is better in assisted motor training, which is very important for the remodeling of the nervous system and the formation of correct sensory-motor circuits: help: At the same time, the upper limb rehabilitation training robot is a rehabilitation training product related to the safety of users, and it is subject to scientific and strict quality technology: Supervision is very necessary, the formulation of this document will play a positive role in the improvement of the quality of the upper limb rehabilitation training robot and the regulation of the market effect: The upper limb rehabilitation training robots produced by different manufacturers have different structures, types, and expected functions: The type and specific requirements of the robot can be applied in whole or in part to the requirements and test methods described in this document: When specific upper extremity rehabilitation training When the protective measures taken by the training robot are inconsistent with the safety requirements and/or protective measures specified in this

document, a risk assessment is required to Determine if the protective measures taken are appropriate: Future versions of this document may include specific requirements for specific classes of upper extremity rehabilitation training robots, as well as applications for different classes population with more complete data (eg, children, the elderly, pregnant women): Requirements and test methods for upper limb rehabilitation training robots

1 Scope

GB/Z 41046-2021 is the Chinese national standard on rehabilitation robot for upper limb training - requirements and test methods, in the field of health care technology. The /Z suffix marks it as a guiding technical document: it does not prescribe requirements that can be certified against, but sets out the technique, the method or the state of the art that the standards bodies recommend following. It was issued on 31 December 2021 by the State Administration for Market Regulation, Standardization Administration of China. As a guiding technical document it carries no separate date of entry into force: it applies from publication. Classification: ICS 11.180, CCS C45. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document specifies the requirements and test methods for the upper limb rehabilitation training robot (hereinafter referred to as the robot): This document is applicable to robots that carry out physical rehabilitation training through motion under the guidance of rehabilitation physicians or nursing staff: A single-joint upper limb rehabilitation training device or system with only a fully passive training mode:

2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text: Among them, dated citations documents, only the version corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies to this document: GB 4706:

1 Safety of Household and Similar Electrical Appliances Part 1: General Requirements GB/T 5226:

1 Mechanical and Electrical Safety Mechanical and Electrical Equipment Part 1: General Specifications GB 9706:

1 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance GB/T 10357:

3 Furniture Mechanical Properties Test Part 3: Strength and Durability of Chairs and Stools

GB/T 16754 Design principles of mechanical safety emergency stop function GB/T 16886:

1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing in Risk Management Process

YY/T 0316 Application of Medical Device Risk Management to Medical Devices

YY0505 Medical Electrical Equipment Part 1-2: Collateral Standard for General Safety Requirements: Electromagnetic Compatibility Requirements and Tests

3 Terms and Definitions

The following terms and definitions apply to this document: 3:

1 Upper limb rehabilitation training robot rehabilitationrobotforupperlimbtraining Equipment designed and manufactured based on robotics for rehabilitation training of the upper extremity nervous and muscular system: 3:2 user user A person using a robot for rehabilitation training: 3:3 operator operator The person who sets the operation parameters of the robot and controls the program execution process: 3:4 back-drive The power is applied from the output end of the robot transmission mechanism to drive the driving mode of the input end of the transmission mechanism: 3:5 passive exercise training The power comes from the robot, and the robot exerts force on a certain part of the human body, thereby driving the joints of the limbs to make coherent movements: