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GB/T 44423-2024

**General requirements for near-infrared brain function
rehabilitation assessment equipment**

近红外脑功能康复评估设备通用要求

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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 is required. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is issued by the Ministry of Civil Affairs of the People's Republic of China. This document is under the jurisdiction of the National Technical Committee for Standardization of Rehabilitation and Special Equipment for Persons with Disabilities (SAC/TC 148). This document was drafted by: National Rehabilitation Assistive Devices Research Center, Danyang Huichuang Medical Equipment Co., Ltd., Beijing University of Aeronautics and Astronautics, Zhongshan The Third Affiliated Hospital of University of Science and Technology, Suzhou Aiqin Biomedical Electronics Co., Ltd., Zhongguancun Medical Device Industry Technology Innovation Alliance, Beijing Social Management Vocational College of Science, Zhejiang Puco Medical Technology Co., Ltd., Zhengzhou Renhui Medical Technology Co., Ltd., Anhui Harbin Institute of Technology Peugeot Medical Health Products Co., Ltd. Industry Co., Ltd. The main drafters of this document are. Zhang Tengyu, Li Zengyong, Wang Daifa, Li Wenhao, Fu Qijun, Pan Guoxin, Zhang Jingsha, Xu Gongcheng, Li Xin, Li Yue, Qin Yongqing, Zhu Huai, Guan Shichang, Xiao Hongbo. General requirements for near-infrared brain function rehabilitation assessment equipment

1 Scope

GB/T 44423-2024 sets the general requirements for near-infrared brain function assessment equipment used in rehabilitation. Functional near-infrared spectroscopy measures cortical haemodynamics through the intact scalp, and because it tolerates movement far better than fMRI it has become the practical way to observe brain activity during the movement, speech and gait tasks that rehabilitation actually consists of. The

standard sets the classification, by structure and by light source type, and the composition of the equipment, then the requirements: the optical source and detector characteristics, the wavelengths and their stability, the sensitivity, signal-to-noise ratio, dynamic range and sampling rate, the optode arrangement and its registration to the head, the crosstalk and motion artefact behaviour, the data output and the algorithms, the electrical safety and electromagnetic compatibility, the optical radiation safety at the scalp, and the environmental and reliability requirements. It then gives the test methods, the inspection rules and the marking and accompanying documents. It took effect on 23 August 2024.

This document specifies the classification, composition, and requirements of near-infrared brain function rehabilitation assessment equipment (hereinafter referred to as "equipment"), and describes the corresponding The test method is specified, and the inspection rules, marking, instruction manual, packaging, transportation and storage are stipulated. This document applies to the use of near-infrared spectroscopy technology to study movement, cognition, mental disorders, etc. caused by brain damage, developmental disorders or lesions. The design, production, testing and use of equipment used to assess brain function during rehabilitation.

2 Normative references

The contents of the following documents constitute the 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. in this document.

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

GB/T 4208 Enclosure protection degree (IP code)

GB 7247.1 Safety of laser products Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Near-infrared brain function rehabilitation assessment equipment near-infrared brain function rehabilitation assessment equipment The near-infrared cerebral blood oxygen collection system is used to obtain the relative changes in the distribution of cerebral blood oxygen content in the surface area of the cerebral cortex, which reflects the brain function. Device that can recover from the condition.

3.2 Near-infrared brain blood oxygen acquisition system A device for measuring changes in brain tissue hemoglobin concentration using near-infrared spectroscopy technology.

Note. Its working principle is to transmit the spectrum into the brain tissue and detect the

changes in the intensity of infrared and visible light diffusely reflected from the brain tissue to calculate the brain Changes in tissue hemoglobin concentration (oxyhemoglobin, deoxyhemoglobin, total hemoglobin).

3.3 emitter probe The component of the near-infrared cerebral blood oxygen collection system, which is used to transmit the spectrum to the living tissue, constitutes the application part of the system.