

ICS 11.040.01
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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 46857.1-2025

**Medical equipment operation and maintenance services - Part
1: General requirements**

医疗装备运维服务 第1部分：通用要求

Issued on: December 31, 2025

Implemented on: July 1, 2026

**Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC**

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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 Part 1 of GB/T 46857 "Operation and Maintenance Services for Medical Equipment". GB/T 46857 has already published the following parts.

1. General 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 and is under the jurisdiction of the National Medical Equipment Industry and Application Standardization Working Group (SAC/SWG26). This document was drafted by: the Institute of Comprehensive Technology and Economics of Instrumentation and Meter of the Machinery Industry, Beijing Friendship Hospital affiliated to Capital Medical University, and Southern... Southern Medical University Hospital, Beijing Tsinghua Chang Gung Hospital, Peking University Third Hospital, Shanghai United Imaging Healthcare Co., Ltd., Shanghai Kedou Medical Technology Co., Ltd., National Institute of Metrology, Shenzhen Institute of Metrology and Quality Inspection, Weihai Maternal and Child Health Hospital, Kunshan Medical Yuan Medical Technology Co., Ltd., Baoding Second Hospital, West China Hospital of Sichuan University, and the First Affiliated Hospital of Shandong First Medical University (Shandong Province) Foshan Hospital), the First Affiliated Hospital of Zhejiang University School of Medicine, Harbin Sizherui Intelligent Medical Equipment Co., Ltd., and Meikang Biotechnology Co., Ltd. Limited Liability Company, Shandong University, Shandong Medical Engineering Technology Co., Ltd., Shenzhen Anter Medical Co., Ltd., Shenzhen BGI Genomics Technology Co., Ltd. Limited Liability Company, Siemens Healthineers, CGN Medical Technology (Mianyang) Co., Ltd., GE Healthcare Technology Services (Tianjin) Co., Ltd. Tianjin (Tianjin) Co., Ltd., Coronos Medical Devices (Shanghai) Co., Ltd., Shenzhen Inmeda Medical Technology Co., Ltd., Tonghua Hainda High-Tech Co., Ltd. Limited Liability Company, Elekta (Beijing) Medical Devices Co., Ltd., Beijing Langshi Instruments Co., Ltd., Henan Provincial People's Hospital, Neusoft Medical GE Healthcare Systems Co., Ltd., Institute of Microbiology, Chinese Academy of Sciences, GE Healthcare Trading Development (Shanghai) Co., Ltd., Nanyang Medical Higher vocational colleges, Jiangxi Nanhua Pharmaceutical Co., Ltd., Shandong Yiyang Intelligent Technology Co., Ltd., Elekta (Shanghai) Medical Devices Co., Ltd. China Electronics System Engineering Third Construction Co., Ltd., Yunnan Fuwai Cardiovascular Hospital, Zhuhai Quanshitong Information Technology Co., Ltd., and Erdos... Dos Central Hospital (Inner Mongolia Autonomous Region Ultrasound Imaging Research Institute), Shenzhen Longhua District Central Hospital, Ninghai County First Hospital, Fujian Jinuo Houpu Biotechnology Co., Ltd., Shenzhen New Industries Biomedical Engineering Co., Ltd., Shandong Xinhua Medical Instrument Co., Ltd. Meditech Medical Technology Service (Shanghai) Co., Ltd., Jointown (Wuhan) Medical Equipment Service Co., Ltd., Lanzhou Taiji Ion Technology Co., Ltd. Company, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Tianjin Medical Device Quality Supervision and Inspection Bureau Testing Center, Philips (China) Investment Co., Ltd., Olympus (Beijing) Sales and Service

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Medical equipment refers to the total amount of hardware, software, and integrated systems developed and applied to safeguard the lives and health of the people. Maintenance and operation services are crucial for ensuring the safety and effectiveness of medical equipment. In practice, the quality of maintenance and operation services for medical equipment... A decline in performance can lead to performance and safety issues in medical equipment. To improve the quality of operation and maintenance services, standardize medical equipment operation and maintenance practices, and ensure... The draft document ensures that medical equipment meets usage requirements and is safe and effective. GB/T 46857 "Operation and Maintenance Services for Medical Equipment" is proposed to consist of three parts.

1.General Requirements. The purpose is to standardize the objectives, principles, and requirements of medical equipment operation and maintenance services, and to guide the operation and maintenance system. Establish and operate the management system, and provide detailed specifications for the service capabilities within the operation and maintenance system.

2.Operations and Maintenance Personnel Competency Requirements. The purpose is to set requirements for personnel working within the operations and maintenance system.

3.Methodology for Evaluating the Quality of Operation and Maintenance Services. The

purpose is to propose evaluation indicators and methods for the quality of operation and maintenance services. Medical equipment operation and maintenance services Part

1 Scope

GB/T 46857.1-2025 is the Chinese national standard covering maintaining the equipment of a hospital - the inventory and its risk classification, the planned maintenance and performance verification, the response to a failure on equipment a patient is attached to, the spare parts and the records. Part 1 of the series, first edition. It was issued on 31 December 2025 and has been in force since 1 July 2026, as a first edition. The document is under the responsibility of the Standardization Administration of China. This page is published from the official record of the 2025 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document specifies the general requirements for medical equipment operation and maintenance services, including overall requirements, objectives and plan requirements, resource allocation requirements, and implementation. Requirements, quality management, etc. This document applies to the planning, implementation, operation, and management of medical equipment maintenance services, and also serves as a reference for medical equipment users in selecting maintenance service providers. The basis for the service provider's decision.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 User unit Organizations that use medical equipment to carry out medical treatment, teaching, scientific research, prevention, and healthcare work.

3.2 Activities conducted after the delivery and acceptance of medical equipment to ensure that the medical equipment is in a safe and effective state. Examples. such as inspection, testing, calibration, maintenance, repair, etc.

3.3 Organizations that provide medical equipment operation and maintenance services to users.

Note. This includes the operation and maintenance management department of the user unit, medical equipment manufacturers, or service organizations with the necessary conditions and capabilities.

3.4 Maintenance is performed at predetermined time intervals or according to established