

# Measurement and Testing and Quality Control of Medical Equipment in Medical Institutions

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**To cite this article:**

Li Xiongxing. Measurement and Testing and Quality Control of Medical Equipment in Medical Institutions. *American Journal of Biomedical and Life Sciences*. Vol. 11, No. 4, 2023, pp. 60-64. doi: 10.11648/j.ajbls.20231104.11

**Received:** July 4, 2023; **Accepted:** July 26, 2023; **Published:** July 27, 2023

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**Abstract:** *Objective:* Improve the overall operational quality and development efficiency of medical institutions, enhance the level of medical equipment testing technology and safety quality control, and form a sustainable development model for the medical industry. *Methods:* Analyze the problems of insufficient professional technology in medical equipment testing management in medical institutions, limited scientific level of metrological testing, and inadequate implementation of medical equipment testing supervision, and seek solutions for standardized testing steps, acceptance quality testing (metrological testing), status testing, and stability testing. *Results:* Formulate medical equipment testing and safety quality control measures, including continuously increasing the importance of medical equipment quantity testing, strengthening the implementation of measurement testing supervision and management, establishing a sound medical equipment measurement and detection mechanism, Innovation management mode and using information technology. *Conclusion:* By analyzing the countermeasures for medical equipment testing and safety quality control, strengthening the implementation of metrological testing supervision and management, and establishing a sound mechanism for medical equipment metrological testing, we can improve the collaborative control of medical safety, promote medical safety quality control work, ensure that the effectiveness of hospital medical equipment testing and safety quality control meets the expected requirements, and improve the level of medical equipment testing and safety quality control work.

**Keywords:** Medical Institutions, Medical Equipment, Metrological Testing, Quality Control, Countermeasure Analysis

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## 1. Introduction

With the gradual deepening of the concept of professional management throughout the entire life cycle of medical equipment, regulations, policies, and industry norms related to quality control of medical equipment have been successively promulgated and implemented, such as China's "Measures for Quality Supervision and Management of Medical Device Use" [1]. (Order No. 18 of the State Food and Drug Administration) clearly requires that "medical device users shall inspect, inspect, calibrate, and record medical devices that require regular inspection, inspection, and calibration in accordance with the requirements of the product manual, and conduct timely analysis and evaluation to ensure that the medical devices are in good condition"; The testing and safety quality of medical equipment in medical institutions are related to the life and health of patients and the actual service quality of medical institutions.

As far as the current reality is concerned, with the passage of time, medical institutions in China have continuously updated and improved their testing of medical equipment. However, in the diagnosis and treatment process of medical institutions, due to inadequate testing and safety quality control of medical equipment, there are still relatively many problems that have affected public recognition of medical institution services, and also posed certain obstacles to the formation of sustainable development models in the medical industry. [2-3].

## 2. The Significance of Medical Equipment Testing and Safety Quality Control in Medical Institutions

At present, there has been a significant increase in both the quality and scale of medical equipment in China compared to

the past. The continuous growth in medical demand has created favorable conditions for the diversified development of medical equipment functions, and the value of medical equipment in various aspects such as diagnosis and treatment and monitoring has been fully realized. At the same time, the use and management of medical equipment in medical institutions have also become a key concern in the medical process. Ensuring the professionalism and reliability of medical equipment testing and safety quality control in medical institutions has become a necessary condition for stable operation and sustainable development of medical institutions. Therefore, the testing and safety quality control of medical equipment in medical institutions are irreplaceable, and they have significant practical significance in ensuring the stable operation of medical equipment, reducing medical risks, and promoting the overall medical safety of medical institutions [4].

### **3. Development Characteristics of Medical Equipment Testing and Safety Quality Control in Medical Institutions**

Precision and intelligent medical equipment in medical institutions is a direct reflection of the development of medical technology today. In order to ensure the stable operation of medical equipment, fully utilize its functional value, and reduce any potential medical risks during the period, the concepts of medical equipment testing and safety quality control in medical institutions have been rapidly promoted and popularized. At present, the development characteristics of medical equipment testing and safety quality control in medical institutions in China are mainly manifested in ensuring the safety of medical equipment and promoting the professional use of diagnostic and treatment process equipment. Specific manifestations include: clarifying the quality control, maintenance, and upkeep of the application process of instruments and equipment, conducting periodic medical equipment testing, determining equipment quality parameters and performance indicators, and comparing and judging the degree of equipment qualification based on the original technical indicators [5].

### **4. Steps and Methods for Testing Medical Equipment in Medical Institutions**

#### **4.1. Testing Steps**

The steps for testing medical equipment in medical institutions are as follows: first, comprehensively record and analyze the overall data information of the equipment, and then evaluate and confirm its actual performance through visual inspection, regular maintenance, such as lubrication and adjustment. Then, with the help of electrical safety testing, recording, labeling, etc., comprehensive testing of medical equipment in medical institutions is achieved.

#### **4.2. Acceptance Quality Testing (Measurement Testing)**

There are relatively many testing methods for medical equipment in medical institutions, such as acceptance quality testing (also known as measurement testing). In the process of equipment installation and acceptance, a comprehensive test shall be carried out according to the confirmed process and relevant regulations and standards, and the test results shall be included as the basic reference data for subsequent equipment testing. Large medical equipment (such as computer tomography (CT) equipment) must follow the relevant requirements for testing, the meter must be around the relevant measurement and testing regulations to complete the first test, and imported equipment must be completed in accordance with the relevant standards for commodity inspection, can also take the product manufacturer's technical specifications indicators, or contract technical parameters to complete the corresponding testing work [6].

#### **4.3. State Detection**

As one of the testing methods of medical equipment, state detection is mainly to carry out comprehensive performance testing of the corresponding testing medical equipment when specified and regular. For example, regular detection of medical equipment with the help of measuring instruments belongs to the intuitive display of state detection. In the process of status detection, the corresponding personnel must operate reasonably and in accordance with the requirements of relevant regulations. Any problem in any link will lead to the occurrence of inaccurate final test results.

#### **4.4. Stability Detection**

Stability testing belongs to the daily testing content of medical equipment testing in medical institutions. During the use cycle of medical equipment, comprehensive monitoring and analysis of its relevant indicators must be carried out, and the general level is relatively low. For example, compared to state detection, stability detection is easier to operate and has relatively fewer detection items. However, due to its daily detection scope, the detection frequency is relatively high. During practice, it is necessary to determine whether the system performance and initial state are within the normal range of changes. Usually, the stability testing of medical equipment is mainly carried out by personnel from the medical institution's instrument usage department or relevant engineering and technical personnel.

### **5. Analysis of Problems in the Testing and Management of Medical Equipment in Medical Institutions**

#### **5.1. Lack of Medical Equipment Testing Expertise**

There are relatively various problems in the management of medical equipment testing in medical institutions, among which the most common is the lack of professional

technology in medical equipment testing. During the actual equipment testing in medical institutions, some testing personnel have limited medical knowledge and professional quality, leading to their lack of understanding of the characteristics, principle and structure of medical equipment, and some personnel are not in place. All of these will cause conditions that affect the authenticity and accuracy of the final measurement and detection results. Some medical institutions measurement and testing technology is lagging behind, insufficient attention to medical equipment testing, that medical equipment testing is only a formal work, over time, medical equipment measurement and testing quality, detection accuracy will continue to reduce, it is difficult to eliminate the quality of medical equipment into medical institutions from the source. In particular, some small medical institutions medical equipment, because of the high cost of testing, and the lack of reasonable introduction of advanced technology, the level of measurement and testing technology can not be effectively updated for a long time, the level of diagnosis and treatment detection of medical institutions will also decline, and ultimately is likely to lead to the occurrence of frequent problems such as delayed detection of patient test results and medical safety risks [7].

### ***5.2. The Scientific Degree of Measurement and Testing Is Limited***

The scientific degree of measurement and testing of medical equipment in medical institutions is limited, which is the main problem in the management of medical equipment testing in medical institutions in China at this stage. At present, although China's social and economic development is rapid, many medical institutions have also begun to pay attention to the construction of medical supporting facilities, and have begun to introduce more intelligent, modern and high-precision medical equipment. However, the reality is that medical institutions only recognize the advanced functions of medical equipment, but lack objective cognition of medical equipment testing, and do not pay attention to the importance of medical equipment testing as a safeguard measure for the stable operation of medical equipment, leading some medical units to regard metrological testing as a stereotypical form of medical institution inspection, and the inspection process is also a "coping" response. In this process, when medical workers use equipment that is not measured or tested on the go, the incidence of medical risk will become difficult to pre-control, medical safety can not be guaranteed, it is easy to cause diagnosis and treatment errors, and the functional value of the corresponding medical equipment is difficult to effectively play.

### ***5.3. Inadequate Implementation of Medical Equipment Testing and Supervision***

The inadequate implementation of medical equipment testing supervision is also one of the reasons for various medical equipment testing management problems in medical

institutions. Usually, during the update period of medical equipment, some medical institutions will issue specific certificates according to the equipment manufacturer to promote relevant work, but do not conduct secondary inspections of the equipment. This phenomenon of incomplete quality supervision and testing of the medical equipment provided by the manufacturer also lays the groundwork for subsequent equipment quality hazards. At the same time, medical device equipment manufacturers generally conduct routine spot checks before the equipment leaves the factory, without conducting comprehensive inspections, which can easily lead to equipment with poor quality and performance parameters entering medical institutions without testing. However, medical institutions do not have sufficient supervision and implementation when inspecting new medical equipment, and cannot complete relevant testing work in detail and seriously. They only conduct testing step by step, This will lead to the use of substandard medical equipment in the normal operation of medical institutions, which will cause harm and equipment failures, and also have a very negative impact on the overall medical level and subsequent development of medical institutions [8].

## **6. Measures for Medical Equipment Testing and Safety Quality Control in Medical Institutions**

### ***6.1. Continuously Improve the Attention Paid to the Measurement of Medical Equipment Volume in Medical Institutions***

For the medical equipment testing and safety and quality control countermeasures of medical institutions, the practice must start from the level of constantly improving the medical institutions' attention to the measurement and testing of medical equipment. On the basis of clear medical equipment testing steps and related testing methods, relevant practitioners must face up to the core functional value of medical equipment in the process of patient diagnosis and treatment. Clinical treatment in medical institutions is different from that in the past, on the premise of relying on the comprehensive professional quality and clinical experience of doctors, but also refer to the measurement results of medical equipment. Once the medical equipment test data lack professionalism and authenticity, it will not only lead to the actual situation of patients can not effectively reflect, but also cause doctors to miss diagnosis, misdiagnosis, and treatment failure. Therefore, it is necessary to make a full range of subjective and objective evaluation of medical equipment, master the inspection rate and pass rate of medical equipment, and pay attention to the feedback of medical equipment quality information. During the evaluation of medical equipment, medical institutions and related medical institutions must establish the correct awareness of medical measurement and detection, strengthen the content of measurement management regulations, and

follow the specific facts of medical equipment measurement and management [9]. Carry out the procurement, installation and use of medical equipment in different stages of measurement testing. Relevant medical personnel must have a basic understanding of the characteristics and structure of medical equipment, operate the equipment reasonably, avoid any accidents affecting the quality and safety of medical equipment, and ensure that medical personnel have certain metrological testing knowledge and ability. Medical institutions should regularly carry out metrological testing training programs to guide them to learn related knowledge of medical metrology. Improve the attention of all employees in medical institutions to measurement and testing, develop a good sense of measurement and testing, and create a favorable environment for the smooth development of follow-up medical equipment testing and safety and quality control in medical institutions [10, 11].

### ***6.2. Strengthen the Implementation of Measurement, Testing, Supervision and Management***

Strengthen the implementation of measurement, testing, supervision and management. As far as the current reality is concerned, the advanced medical technology and medical equipment used in modern clinical medicine in China have been normalized. In addition, under the current market economy conditions, medical equipment is the core guarantee for medical institutions to improve their market competitiveness and participate in market competition, and improve the operation reliability, stability and safety of medical equipment in medical institutions. So that it can give full play to its function in the diagnosis and treatment process has become the focus of attention of various medical institutions. Therefore, in order to avoid various risks of medical equipment and fully demonstrate its value, medical institutions must establish a professional medical equipment maintenance mechanism and regular medical equipment testing system to ensure the effectiveness of medical equipment use. In terms of measurement testing, a complete supervision and management program must be equipped to eliminate the use of medical equipment that does not meet the measurement and testing standards. The medical equipment that does not meet the measurement and testing standards shall be disposed of for the first time. In addition, the supervision and management of medical equipment quality control and safety assurance are improved, and the effectiveness of medical equipment measurement and testing is continuously promoted over time, so as to achieve the purpose of continuously improving the stability and safety of medical equipment in medical institutions and extending the service life of medical equipment.

### ***6.3. Establish a Sound Measurement and Testing Mechanism for Medical Equipment***

Establish a sound measuring and testing mechanism for medical equipment. At present, medical equipment is very common in the clinical application of medical institutions and

has become one of the important carriers of medical diagnosis and treatment. Therefore, from the perspective of scientific use of medical equipment and prevention of medical risks, it is clear that the measurement and detection of medical equipment and safe and reliable medical equipment have a substantial impact on the medical level of medical institutions. At the same time, the measurement and testing standards of medical equipment will continue to improve with the development of science and technology and other factors, so the management of medical equipment measurement and testing must be real-time, accurate and professional. During the practice period, corresponding environmental medicine measuring rooms can be set up in the medical institutions and medical institutions where the medical devices are located, professional metrologers can be arranged, and pre-service training plans for metrologers can be set up to improve the testing level of corresponding personnel. On this basis, in accordance with the current relevant national medical equipment management regulations, the medical device measurement and testing mechanism is established to ensure that medical equipment measurement and testing have rules and standards for reference and laws to strengthen the effectiveness of medical institutions commonly used medical equipment measurement and inspection. With the passage of time, the authenticity, professionalism and accuracy of the measurement and testing results of medical equipment in medical institutions can be effectively guaranteed.

### ***6.4. Innovate Management Models to Improve Coordinated Medical Safety Control***

Innovative management mode to improve medical safety collaborative control, for medical institutions medical equipment testing and safety quality control, on the basis of clear process demonstration and acceptance rules and regulations, medical institutions must pay attention to the training and external introduction of testing talents and other related engineering and technical personnel. For example, in the evaluation and acceptance stage of the establishment of medical equipment, we actively entrust a third-party institution that meets the national testing standards to do a good job in the acceptance and testing of relevant medical equipment. On the basis of passing the test, we will issue the report results according to the testing party to promote the follow-up work. In the selection and demonstration stage, unqualified medical devices can not participate in the bidding review, installation and acceptance of unqualified equipment will not be used. In the subsequent equipment operation stage, the coordination and communication efficiency of various departments of medical institutions should be further promoted by focusing on the standards of quality, performance, safety and effectiveness, and the standard of measurement and verification standards, and the management form of multi-department cooperation and fine control should be gradually formed. After each verification, the use status mark should be affixed, and the relevant equipment users should do a good job in each handover. Medical equipment that is not verified or tested or fails to meet the standards cannot be used, so as to build a

good medical safety collaborative management and control mode, and avoid potential adverse safety risks and accident risks that may occur in the use and management of medical equipment to the maximum extent [12].

### 6.5. Promote Medical Safety Quality Control by Means of Information Technology

With the help of information technology to promote medical safety quality control work, under the background of the current information age, the intelligent and modern characteristics of medical equipment are becoming more and more obvious, and the workload of the medical equipment department is large and cumbersome, which undoubtedly increases the work pressure of medical equipment testing personnel, and will also lead to a significant increase in the phenomenon of manual errors in medical equipment testing. Therefore, medical institutions must keep up with the development requirements of The Times and establish a system platform where all departments can share information resources to liberate the human resources of medical institutions. For example, through the construction of an exclusive information system platform, To further standardize the management process and promote the accuracy of medical equipment testing and safety quality control in medical institutions by connecting the contents of medical institutions' equipment procurement, warehousing, receiving, allocation, maintenance, scrapping, cleaning, testing, supervision and other links as well as the use departments, financial departments and state-owned assets management departments. This is also a key path to achieve dynamic and comprehensive quality management in the life cycle of hospital medical equipment [13].

## 7. Summary

In summary, through the analysis of medical equipment testing and safety and quality control policies for medical institutions, it can be seen that the problems existing in the medical equipment testing management of medical institutions in China at this stage are mainly manifested as insufficient professional technology for medical equipment testing, limited scientific degree of measurement testing, and inadequate implementation of medical equipment testing and supervision. During the practice, it is necessary to continuously improve the attention paid to the quantity testing of medical equipment in medical institutions, strengthen the implementation of measurement testing supervision and management, establish a sound measurement and testing mechanism for medical equipment, innovate the management mode to improve medical safety collaborative control, and promote medical safety quality control with the help of information means. Only in order to ensure that the medical equipment testing and safety quality control effect of medical institutions meet the expected requirements, which is also the basic condition for the continuous improvement of the level of medical equipment testing and safety quality control of medical institutions in China [14, 15].

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