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Development of Recommendations for Ensuring the Reliability of Vertibrological Medical Devices in Accordance With International Standards

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Abstract: *This article examines the issues of developing recommendations in accordance with international standards for assessing and ensuring the reliability of vertebrological medical devices. Apparatus used in the diagnostic and treatment processes related to the spine in medicine must be highly safe and resilient for human health. The article describes methodological approaches in accordance with maintenance, testing, quality management, and safety standards, based on ISO, IEC, and other important international standards. Also, the current situation in the conditions of Uzbekistan was analyzed, and adapted recommendations were developed.*

Keywords: *vertebrology, reliability, maintenance, safety, international standards, ISO, IEC, fault detection.*

Introduction.

Vertebrology is a field of medicine specializing in the diagnosis and treatment of diseases of the spine, in which the medical and technical means used (for example, traction devices, diagnostic tables, physiotherapeutic devices) directly affect the fragile parts of the human body. Therefore, the reliability, accuracy, and safety of this type of equipment are among the most important requirements. Approaches based on international standards play an important role in assessing the reliability of modern medical equipment [1,2].

Today, worldwide, these international standards (ISO 13485, IEC 60601, ISO 14971) are aimed at ensuring safety and functionality at all stages of the life cycle of medical equipment. Within the framework of this article, recommendations are developed based on the requirements of international standards specifically for vertebrological devices [3-5].

Types of vertebrological devices and their technical characteristics

Vertebrological devices are subdivided into the following types:

- *Traction (drawing) equipment*
- *Physiotherapeutic laser and electrotherapy devices for the spinal cord*
- *Diagnostic devices (e.g. vertebral ultrasound devices, MRI)*
- *Rehabilitation simulators*

Reliability in the operation of these devices is an indicator related to uninterrupted operation, accuracy, and the minimal level of technical malfunctions.

The following can be included in the international standards used to ensure the reliability of medical equipment [6,7].

The following basic international standards are important for vertebrological apparatus:

- ISO 13485:2016 - Quality management system for medical equipment.
- IEC 60601-1 - General Safety of Medical Electrical Devices.
- ISO 14971 - Risk Analysis and Risk Management for Medical Devices.
- ISO 10993 - Biological Compliance Analysis.
- IEC 62366 - User Interfaces and Ergonomics.

For the effective organization of work on the timely maintenance of vertibrological medical devices in order to ensure their reliable and efficient operation in the process of operation, the following main stages should be implemented [8]:

1. Planning: The main stage of maintenance consists of planning, which clearly defines the frequency, procedure, responsible persons, and work to be performed for each piece of equipment.
2. Preparatory work: Before service provision, technical personnel are provided with necessary tools, spare parts, and technical documentation.
3. Equipment inspection: During maintenance, equipment is checked for technical condition, and if necessary, diagnostic work is carried out.
4. Detection and correction of malfunctions: If a malfunction is detected during maintenance, it is eliminated or immediate repair work is carried out without interrupting maintenance.
5. Control and reporting: Upon completion of the technical service, a report is compiled based on the results and recorded in special journals. This will serve as the basis for further services.

Documentation process

An integral part of the process of maintenance of medical equipment, taking into account the above-mentioned stages, is documentation. At the same time, the following documents are kept:

Table 1

Document type	Content
Maintenance log	A record is made of each service provision. Date, type of work, completed work, participants are indicated.
Equipment passport	All technical information about the equipment, the list of services, and historical data are stored.
Acts	In case of repair or replacement, special acts are drawn up and approved by management.
Orders and invoices	It reflects the purchase of spare parts and the cost of services.

The most frequently used instrument in the vertebrology department is the traction table. The following practical processes are observed in the organization of its maintenance [9.10]:

- At the beginning of each month, the sensor, electrical cables connected to the motor, and drivers are checked on the table.
- The doctor using the device is asked for feedback - whether there are any vibrations, strange sounds during startup, or stops.

- If necessary, the software will be updated (for some electronic block models).
- The reserve for spare parts - assembly, relay, intermediate - is checked. Practical organization of maintenance work requires not only adherence to theoretical guidelines, but also working in a mode adapted to the real situation. The established services ensure continuity in the provision of medical care to patients, and also guarantee the use of reliable instruments by medical personnel.

The uninterrupted operation of equipment, the stability and safety of its functional state depend precisely on how the maintenance system is organized. Therefore, every medical institution must pay close attention to technical services.

Recommendations for improving the reliability of medical devices that meet international standards:

1. Development and implementation of a national quality management system based on the requirements of ISO 13485
2. Development of a metrological monitoring system for the operation of medical equipment.
3. Improvement of the qualifications of persons responsible for medical equipment in healthcare institutions in accordance with international requirements.
4. Recommendation of periodic calibration and testing of vertebrological equipment
5. Based on international standards in the development of national standards for medical devices.

The uninterrupted operation of vertobrological equipment, the stability of its functional state, and safety depend precisely on how the maintenance system is organized. Therefore, every medical institution must pay close attention to technical services.

Table 2

Name of the instrument/equipment	**Defect type**	**Cause of occurrence**	**Method of elimination**	**Responsible person/department**	**Explanation**
X-ray machine	Low image quality	Sensor dusting or setting errors	Clear sensor, reset settings	Biotechnical personnel	Maintenance recommended every 2 weeks
MRI machine	Cooling system malfunction	Freon leak or fan failure	Cooling system cleaning, Freon gas filling	Service Engineer	Full diagnostics are required at least once a year
Traction table	No movement	Electrical system failure or engine failure	Replacement of the actuator or repair of the motor	Maintenance Department	The electronic block must be checked regularly.
Ultrasonic device	Alarm will disappear	Sensor cable interruption or software failure	Cable replacement, software reboot	Service worker	If the cables are bent incorrectly, they will quickly fail.

Electrotherapy Device	No current	Contact oxidation or internal electronic block failure	Clear contacts, switch electronic module	Biotechnician	The device must undergo an electrical test monthly.
Laser stimulator	It won't start	Power unit malfunction or software error	Replace power unit, restart software	Developer and technician	Often occurs after power outages
Vibro massage table	Insufficient body vibration	Engine failure or braking	Engine replacement or repair	Electrical Equipment Department	The depreciation system will also be checked
EMG (Electromyography) device	Alarm is noisy or interrupted	Electrodes are unusable, loose	Electrode replacement or inspection	physiotherapist	Electrodes must always be disinfected.

Proper design of the service room is crucial for ensuring the effective and safe operation of medical equipment . This room will be designed for **diagnostics, maintenance, repair, calibration, and maintenance documentation** .

Service room on medical equipment and apparatus:

- Maintenance
- Scheduled repair
- Diagnostic tests
- Replace spare parts
- It is a specially equipped technical zone for performing calibration and testing work.

Conclusion

Ensuring the reliability of vertebrological medical equipment is one of the important factors guaranteeing not only the quality of medicine, but also the safety of the patient. Approaches based on international standards ensure high-quality operation of these devices throughout their life cycle. In the conditions of Uzbekistan, it is possible to significantly increase the effectiveness of vertebrological devices by implementing international standards, modernizing national technical regulations, and the certification system. The recommendations presented in this article lay the groundwork for our country to align with international requirements in the field of medical technology.

In conclusion, through this article, proposals and recommendations were developed to ensure the level of reliability of medical equipment used in the Vertebrology Department. Factors influencing the reliability of devices were analyzed, and the need for monitoring and diagnostic methods for their identification and elimination was substantiated.

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