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Application of New Technologies to Improve the Metrological Characteristics of Medical Devices

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Abstract. *In the modern healthcare system, the accuracy and reliability of medical devices are considered key factors determining the effectiveness of diagnostic and treatment processes. The metrological characteristics of medical measurement systems are essential indicators that ensure the functional quality of these devices and the accuracy of clinical results. Metrological assurance encompasses the organization of measurement processes based on scientific principles, the maintenance of measurement accuracy, and the assurance of result reliability. The measurement accuracy, range, sensitivity, stability, and repeatability of results are of particular importance in the clinical application of medical devices. This article examines the application of modern technologies, including sensor systems, artificial intelligence algorithms, IoT-based monitoring solutions, and digital calibration methods, to improve the metrological performance of medical devices. It also considers the role of calibration in comparing measurement results with reference measurement standards and identifying potential measurement errors. The findings indicate that the use of these technologies can improve the measurement accuracy of medical devices, minimize errors, and enable real-time monitoring. Such approaches can enhance the effectiveness of metrological assurance and positively contribute to the reliability of diagnostic decisions and the overall quality of healthcare services.*

Keywords: *medical devices, metrological characteristics, calibration, sensor technologies, artificial intelligence, IoT systems*

Introduction

Metrological assurance is a comprehensive system of activities designed to organize measurement processes in accordance with scientific principles and to maintain the accuracy of the results obtained. The primary objective of metrological assurance for medical devices is to ensure the reliability of measurement results used in diagnosis and treatment. The accuracy and stability of medical measurement systems directly affect the overall quality of healthcare services. Therefore, the scientific study and improvement of the metrological characteristics of medical devices play an important role in the development of modern medical technologies (Morris & Langari, 2016). The metrological characteristics of medical devices comprise a set of parameters that describe the technical and functional performance of a measurement system. These parameters include measurement accuracy, measuring range, sensitivity, stability, and repeatability. Maintaining these indicators at an optimal level helps ensure the reliability of medical devices in clinical use. Since a large proportion of medical equipment used in modern healthcare is based on complex measurement and data-processing systems, the accuracy of its metrological characteristics is particularly important. One of the key stages in the metrological assurance of medical devices is calibration.

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Calibration is performed by comparing the results produced by a measuring instrument with those of reference measurement standards, thereby identifying the instrument's measurement errors. When carried out regularly, this process helps ensure the correct and stable operation of medical devices and substantially improves the reliability of measurement results (Bostani et al., 2025; Chen et al., 2024).

Methods

This study used systematic analysis and comparative research methods to identify the role of modern technologies in improving the metrological characteristics of medical devices. Relevant scientific literature and existing technological approaches were reviewed to identify the principal metrological indicators of medical measurement systems. Sensor systems, artificial intelligence algorithms, Internet of Things (IoT)-based monitoring solutions, and digital calibration methods were compared in terms of their functional capabilities. The comparison focused on measurement accuracy, sensitivity, stability, repeatability, and the reduction of measurement errors. The effect of calibration on the reliability of measurement results and the operational quality of devices was also analyzed. Based on a synthesis of the information obtained, the potential applications of modern technologies for improving the metrological assurance of medical devices were evaluated.

Results

Metrological characteristics are key indicators for assessing the measurement quality and reliability of medical devices. Some of the main quality indicators of measuring instruments are presented in Table 1.

Table 1
Quality Indicators of measuring instruments

Quality indicators	Description and significance
Accuracy	Indicates how close a measurement result is to the true value and supports the correctness of clinical decisions.
Repeatability	Indicates the closeness of measurement results obtained under the same conditions and helps identify whether systematic-error correction may be needed.
Sensitivity	Describes the device's ability to detect small changes and makes it possible to identify sudden changes in a patient's condition.
Stability	Describes the long-term stability of device performance and its consistency over time, supporting metrological reliability.

Source. Prepared by the authors.

At present, the metrological assurance of medical devices is no longer limited to calibration and technical inspection. The rapid development of information technologies has created broad opportunities for automating and digitizing metrological processes. This approach enables more efficient management of medical device operation and real-time monitoring of their technical condition (Bohr & Memarzadeh, 2020).

The development of sensor technologies has played an important role in expanding the functional capabilities of medical devices and improving their metrological characteristics. Modern sensors can measure physiological and biochemical changes in the human body with high accuracy and are therefore widely used in diagnostic and monitoring systems.

Biosensors are among the key components of medical measurement systems. They analyze chemical reactions and biological processes in the body to measure various parameters. For example, glucose sensors enable continuous blood glucose monitoring in people with diabetes. Electrochemical sensors are also widely used to assess cardiac activity and determine blood oxygen levels.

The application of sensor technologies in medical devices offers several advantages. First, these technologies help increase measurement accuracy and minimize errors. In addition, sensor systems provide real-time data acquisition, enabling medical decisions to be made more promptly.

The development of sensor technologies has also made it possible to miniaturize medical devices. Modern portable medical equipment can be used in patients' everyday lives and allows their health status to be monitored continuously. This is particularly important for the management of chronic diseases (Morris & Langari, 2016).

Advances in artificial intelligence have opened up new opportunities for improving medical measurement systems. Artificial intelligence algorithms can rapidly process large volumes of data obtained from medical devices, thereby contributing to increased measurement accuracy.

Machine-learning methods can analyze sensor data and detect anomalies that arise during the measurement process. These algorithms can identify systematic errors and support their correction, thereby substantially improving the metrological performance of medical devices. Artificial intelligence technologies are also used to predict the technical condition of medical devices (Rabus et al., 2025). This approach makes it possible to identify potential malfunctions in advance and carry out preventive maintenance (International Organization for Standardization, 2022).

IoT technologies integrate medical devices into a unified network, making their management more effective. Through this technology, information about the technical condition of devices and their measurement results is transmitted to centralized information systems. IoT-based monitoring systems enable medical equipment to be tracked in real time and its technical performance to be assessed (Shaw & Gohel, 2025).

These systems automatically record the calibration status and technical parameters of devices. The use of IoT technologies not only improves the operational safety of medical devices but also helps optimize maintenance processes. In addition, this approach increases the efficiency of medical equipment management in healthcare institutions (International Organization for Standardization, 2022).

The use of digital calibration technologies is becoming increasingly common in modern metrological systems. Such systems automatically record measurement results and enable their prompt analysis. This approach minimizes the influence of human factors on the measurement process while helping to improve overall measurement accuracy. Digital calibration solutions support continuous monitoring of the metrological indicators of medical devices and make it possible to update and analyze calibration parameters automatically.

The measurement accuracy and functional reliability of medical devices are directly related to patients' health and safety. For this reason, the systematic and continuous improvement of the metrological characteristics of medical equipment is one of the priorities of modern healthcare systems.

The results of the study can be illustrated by the example presented below. The flowchart of the calibration process is shown in Figure 1.

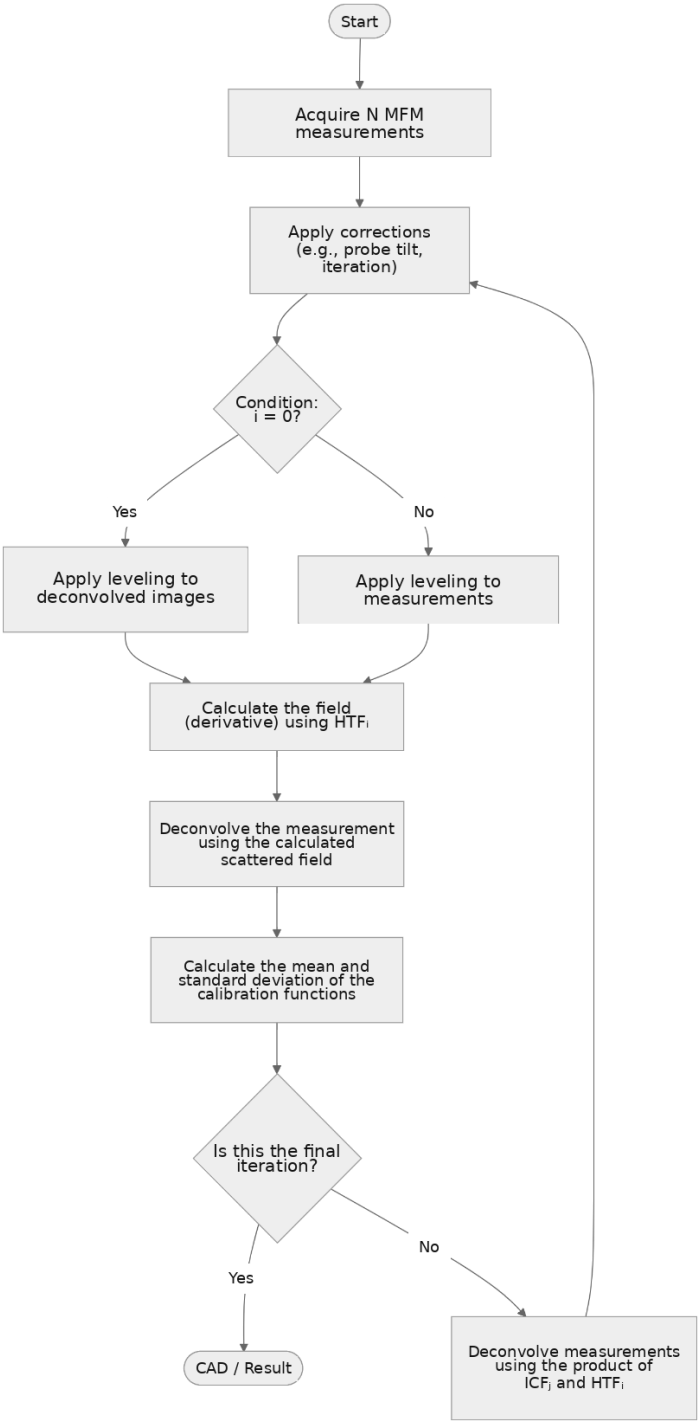

Figure 1
Flowchart of the calibration process

The calibration process is carried out through a staged and iterative approach intended to improve the accuracy of measurement results and ensure that the device correctly represents actual physical signals. The initial stage in the flowchart involves collecting MFM measurements. At this stage, several measurements are performed to create an initial dataset. However, the data obtained are not directly suitable for use because various systematic and random errors may arise during measurement. Therefore, corrections are applied at the next stage. These corrections include probe tilt, deviations arising from the technical characteristics of the device, and inaccuracies introduced during iteration (Taylor & Kuyatt, 1994).

One of the main characteristics of the process is its iterative nature. The decision blocks shown in the flowchart (for example, “j = 0” and “final iteration”) provide this repetition. During the initial iteration, measurements are processed directly; in subsequent stages, more accurate calculations are performed by taking the previous results into account. Leveling is applied to both the initial measurements and the deconvolved images so that all data are brought to a common reference level and can be compared.

At the next stage, magnetization structures are formed, and the field derivative is calculated on the basis of these structures. In this process, the HTF (Height Transfer Function) is used to establish a relationship between the measured signal and the actual magnetic field. The resulting field data are then used in the deconvolution stage. Deconvolution makes it possible to separate the instrument-specific characteristics and external environmental effects from the measurement signal, thereby enabling the actual physical signal to be reconstructed.

The results are then processed statistically. At this stage, the mean and standard deviation of the calibration functions are calculated, making it possible to assess the stability and reliability of the results. If the results do not meet the required level of accuracy, the process proceeds to the next iteration and the calculations are repeated. In the final stage, the measurements are deconvolved again, taking into account the combined effect of the ICF (Instrument Calibration Function) and HTF. This approach makes it possible to account for the instrument-specific characteristics and measurement conditions in an integrated manner, thereby aiming to achieve the highest possible accuracy.

Thus, all the stages presented in the flowchart operate in conjunction to minimize measurement errors and produce reliable results.

Selected Example Device: GE CARESCAPE Monitor B650
- Brand and model: GE Healthcare, CARESCAPE B650
- Measured parameters: SpO_2, ECG, temperature, NIBP
- Calibration instrument: Fluke Biomedical SPOT Light simulator
- Calibration software: GE CARESCAPE Calibration Tool
- Sensitivity level: SpO_2 ±2%, ECG ±0.5 mV

The calibration process is explained step by step below:
Preparation:
- The device is connected to a power source and switched on.
- The sensors are positioned correctly: a finger clip is used for SpO_2, and the ECG electrodes are applied to the chest.
- The calibration software is launched.

Testing with the Simulator:
- The Fluke SPOT Light simulator sends signals corresponding to the device parameters.
- The device readings are compared with the values generated by the simulator.

Adjustments and Optimization:
- Systematic errors are identified using the software.
- The parameters are automatically updated in the device memory.

The SpO_2 calibration results are presented in Table 2.

Table 2
SpO_2 calibration results

Test No.	Simulator result (%)	Device reading (%)	Error (%)
1	95	95.2	+0.2
2	90	89.9	-0.1
3	85	85.1	+0.1
4	80	80.0	0.0
5	75	75.2	+0.2

Analysis of results: The maximum error is ±0.2%; the device meets international standards.
The ECG calibration results are presented in Table 3.

Table 3
ECG calibration results

Test No.	Simulator result (mV)	Device reading (mV)	Error (mV)
1	1.0	1.01	+0.01
2	0.8	0.79	-0.01
3	0.5	0.51	+0.01
4	0.3	0.30	0.00

Analysis of results: The maximum error is ±0.01 mV; the ECG measurements meet clinical reliability requirements.

A graphical representation of the ECG calibration results is shown in Figure 2.

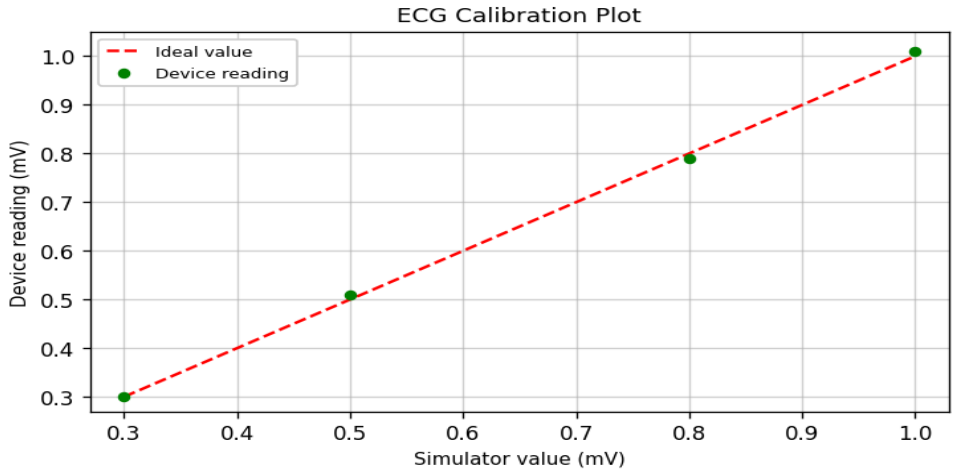

Figure 2
Graphical representation of the ecg calibration results

– X-axis: simulator values (mV)
– Y-axis: device readings (mV)

The analysis of the available scientific literature indicates that integrating modern technologies into the metrological assurance of medical devices is important for the development of healthcare systems. The use of sensor technologies, artificial intelligence algorithms, IoT-based monitoring systems, and digital calibration methods can increase the measurement accuracy of medical devices and improve their reliability (Kalantar-zadeh, 2013; Wilson, 2004).

Looking ahead, the wider application of artificial intelligence and Big Data technologies is expected to further improve the metrological characteristics of medical devices. These approaches may contribute to the optimization of measurement processes, more effective error detection, and an overall improvement in the quality of healthcare services (Joint Committee for Guides in Metrology, 2008; Cosoli et al., 2023).

Conclusions

1. The findings of the study show that metrological assurance, particularly calibration as one of its principal stages, is crucial to ensuring the measurement accuracy and reliability of medical devices.
2. Comparing measurement results with reference values, identifying systematic errors, and correcting them are essential conditions for ensuring the proper and stable operation of devices.
3. An iterative calibration approach, the use of deconvolution methods, and the application of calibration functions such as HTF and ICF make it possible to obtain measurement results with greater accuracy. In addition, statistical analysis methods enable the stability and reliability of the results to be evaluated.
4. The calibration results obtained from the selected medical device as a practical example indicate that properly organizing the process can produce highly reliable results. The identified measurement errors are stated to comply with the requirements of international standards and to confirm the device's suitability for clinical use.

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