Legislation of Ukraine requirements on verification of medical devices with measuring function

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Abstract

This article addresses the necessity of verifying medical devices with measuring functionality, highlights key legislative changes, and underscores the requirements for verification at the time of deployment/usage and throughout the operational lifespan of medical devices involving measuring functions.

Legislative changes have led to a lack of awareness among healthcare facilities using medical devices with measuring functions regarding the regulatory requirements, ensuring measurement accuracy for proper diagnosis, diagnostics, monitoring, and treatment.

Therefore, familiarity with legislation and adherence to established requirements enable the implementation of preventive measures to safeguard public health and safety while minimizing risks associated with the use of medical devices.

Thus, this article is crucial for enhancing awareness regarding the verification requirements for medical devices with measurement functions and for the proper fulfillment of responsibilities by facilities employing such medical devices with measuring functions.

Keywords: medical devices, verification of medical devices, initial verification, periodic verification, measuring function.

Abbreviations used:
MI — Measuring instrument;
MoH — Ministry of Health of Ukraine;
MoE — Ministry of Economy of Ukraine;
CMU — Cabinet of Ministers of Ukraine.

1. Introduction

Measuring functionality is incorporated into numerous medical devices such as analyzers, pulse oximeters, cardio defibrillators, electrocardiographs, ultrasound machines, and others. Some medical devices are solely intended for measurements, for example, thermometers and blood pressure equipment.

The reliability and accuracy of measurements from such equipment play a pivotal role in diagnosis, treatment, and prevention. Medical devices must ensure high measurement accuracy both upon their introduction into operation and throughout their entire shelf life.

How is the accuracy of measurements ensured at the time of introducing a medical device into
circulation and operation? What documents are required to confirm this? How often and by what means is the accuracy of measurements verified during the operation of a medical device? What are the responsibilities for violating Ukraine’s legislative requirements regarding verifying medical devices with measuring functions?

In this article, we provide answers to these and other questions regarding the legislative requirements for verifying medical devices with measuring functions.

This article is for informational purposes only and reflects our expert opinion and interpretation of the legislation in effect as of December 1, 2023. For official clarifications, it is necessary to refer to the central executive authorities, particularly the MoE and the MoH.

2. Do the requirements of Ukrainian legislation extend to the verification of medical devices with measuring functions?

The primary legislative act governing metrology and metrological activities is the Law of Ukraine «On Metrology and Metrological Activity» [1].

According to the definition provided in Law [1], MI are measuring instruments, measuring systems, reference samples, and any components of measuring instruments or measuring systems if these components could be subject to specific requirements or separate conformity assessment.

In accordance with Article 3 of Law [1], ensuring the protection of citizens’ lives and healthcare falls within the realm of legislatively regulated metrology.

Therefore, medical devices with measuring functions are also qualified as MIs and should meet the requirements of Ukrainian legislation in the field of metrology and metrological activity, particularly concerning verification.

The purpose of verification is to assess the compliance of metrological and certain technical characteristics of medical devices involving measurements with the requirements of international and national standards, as well as the specifications of companies engaged in the production of medical devices concerning measurement accuracy.

Timely verification enables monitoring the technical condition of medical devices with measuring functions regarding accuracy and, for some, the safety of measurements.

3. Conformity assessment of medical devices with measuring functions

According to Law [1], the conformity assessment of MIs is carried out in cases and according to procedures established in relevant technical regulations.

In accordance with Article 30 of the Law of Ukraine «On Technical Regulations and Conformity Assessment» [2], a conformity assessment with all applied technical regulations is necessary for affixing the conformity mark. This means that the manufacturer or its authorized representative in Ukraine must check all applicable technical regulations and conduct the respective conformity assessment procedures before affixing the conformity mark according to the technical regulations.


Technical Regulations for medical devices [3,4,5] establish requirements for devices with measuring functions, including the production process, to ensure compliance with metrological requirements. During the conformity assessment, the manufacturer or its authorized representative must demonstrate stability and accuracy in measurements within the Essential Requirements checklist and provide evidence in the technical documentation. A notified
Conformity assessment body is involved in conformity assessment of medical devices with measuring functions. However, this is not required for in vitro diagnostic medical devices, and accordingly, most in vitro diagnostic medical devices undergo internal quality control procedures.

Thus, relevant technical regulations \([3, 4, 5]\) contain specific requirements concerning measuring functions, and the assessment responsibility lies with either the notified body or the manufacturer.

Since January 19, 2020, medical devices have been excluded from the scope of Technical Regulation № 94 \([6]\). Consequently, Technical Regulation № 94 \([6]\) does not apply to medical devices, and its requirements should not be considered.

Requirements from other technical regulations, such as Technical Regulation № 139 \([7]\) and Technical Regulation № 355 \([8]\), which could also apply to medical devices, **do not contain any requirements regarding measuring functions**.

The document for conformity assessment, upon which the medical device is placed on the market or put into operation, is a declaration of conformity to all applied technical regulations. By preparing the declaration, the manufacturer of the medical device ensures and guarantees compliance with all applied established requirements and characteristics.

Therefore, a declaration of conformity and, if required by conformity assessment procedures, a certificate of conformity is sufficient for placing on the market or operating medical devices with measuring functions.

4. **Ensuring measurement accuracy**

As previously established, medical devices with measuring functions qualify as MIs but are not covered by Technical Regulation № 94 \([6]\). To ensure compliance of medical devices with measuring functions with metrological requirements, guidance should be derived from Law \([1]\) and relevant subordinate legislative acts.

According to Law \([1]\), MIs in operation are subject to periodic verification and verification after repair.

Verification of MIs is a set of operations that includes examination, marking, and/or issuance of a verification document for MIs, establishing and confirming that the specified instrument complies with the established requirements.

Various types of verification are envisaged, such as post-repair verification, periodic, extraordinary, expert, and inspection verifications. Any MIs may be subject to all types of verification, except for periodic verification, which applies only to MIs included in the list of MI categories according to Resolution № 374 \([9]\).

Medical devices and in vitro diagnostic medical devices listed in Resolution № 374 \([9]\) are subject to periodic verification. Therefore, the accuracy of measurements of medical devices throughout their operational lifespan is ensured through verifications, including periodic ones.

The accuracy of MI measurements is formalized numerically as the metrological characteristics of MIs or measuring functions performed by the medical device. This could include measurement range, maximum permissible measurement error, measurement uncertainty, measurement error limits, and so forth.

Adhering to normative documents and specifications regarding measurement accuracy undoubtedly contributes to the reliability of diagnoses and significantly impacts public health.

5. **Is there an initial verification conducted for medical devices with measuring functions?**

The technical regulations \([3, 4, 5, 7, 8]\) most commonly applied to medical devices do not establish requirements for the initial verification of medical devices with measuring functions. The concept of initial verification emerged from Law \([1]\) as, up to a certain point, Law \([1]\) required conducting such type of verification, namely the initial one.

However, in 2019, based on the Law of Ukraine «On amendments to certain legislative acts of Ukraine regarding the implementation of European Union legislation in the field of technical regulation» \([10]\), Article 16 of Law \([1]\) excluded the provision mandating the requirement for the initial verification.
Currently, Law [1] does not mandate the conduct of the initial verification; hence, there is no legal basis for its execution. Consequently, conducting the initial verification for medical devices with measuring functions before their delivery to the end-user is not mandatory under the current legislation of Ukraine.

Extraordinary verification, as per Section II, Clause 18 of Order № 193 [11], stipulates that MIs held in storage and not in use are not subject to periodic verification but are subject to extraordinary verification immediately before being put into operation or leased out. Such an MI must bear a visible mark indicating it is not in use, only stored. Also, the fact that the MI is in storage and not in use should be documented in an official report.

Thus, even though initial verification for medical devices with measuring functions is not stipulated by legislation, it is essential to consider that in the aforementioned instances, commencing the operation of non-verified devices is effectively prohibited under the Law.

6. How and when is periodic verification conducted?

Article 17 of Law [1] establishes that MIs in use are subject to periodic verification.

According to Law [1], periodic verification of MIs is the process conducted during their operational period through a specified time interval termed the verification interval. Per Resolution № 1195 [12], the verification interval is defined as the period or usage between two successive verifications of an MI within which the metrological characteristics of such an MI must meet the established requirements.

As per Part 3 of Article 17 of Law [1], business entities are obligated to timely submit MIs in use for periodic verification, adhering to the established verification intervals.

Medical devices with measuring functions are subject to periodic verification if included in the list of categories of MIs according to Resolution № 374 [9], with a verification interval established by Order № 1747 [13].

Summing up, the calculation for the first verification starts upon the introduction of the MI into operation. However, if the device has not been in operation (for instance, after purchase) and is in storage, it is advisable to conduct an extraordinary verification before its use. In such a case, considering Clause 18 of Order № 193 [11] and Clause 2 of Resolution № 1195 [12], the verification interval will be calculated from the date of the extraordinary verification.

7. Other types of verifications

In this section, we will briefly discuss other types of verifications, such as post-repair verification, extraordinary verification, expert verification, and inspection verification.

Post-repair verification is conducted after performing repair works, including dismantling, transportation, and reassembly of the MI.

Extraordinary verification is performed when necessary for the applicant to ensure the suitability of the MI for use or in case of damage to the verification mark or loss of the verification certificate.

Expert verification is carried out in the event of disputes regarding metrological characteristics, suitability for use, and the correctness of the operation of the MI.

Inspection verification is performed in the course of metrological surveillance of the conformity of MIs in service, in particular, as part of planned and unplanned inspections by the relevant metrological surveillance authority.

8. Time for verification

According to Order № 1719 [14], established standards regulate the time necessary for the verification of MIs in use. Verification should last several days and not exceed 15 working days after the submission of the MI for verification, and if payment for its conduct has been made in accordance with the provisions of point 12 of Section II of Order № 193 [9].
9. Responsibility for the non-conduct of periodic verifications

In this section, we will consider the responsibility for the absence of periodic verifications of medical devices with measuring functions and consequences.

Obligation of conducting periodic verifications. According to point 13 of Resolution № 285 [15], business entities licensed for medical practice are obliged to conduct periodic verifications of medical devices with measuring functions that are in use, in compliance with established verification intervals. This provides the legal basis for conducting periodic verifications after the introduction of such devices into operation.

Responsibility for non-compliance. Article 16 of the Law «On licensing of types of economic activity» [16] establishes that violation of licensing conditions, including the obligation to conduct periodic verifications, may lead to suspension or cancellation of the license for medical practice, as mentioned earlier.

Administrative responsibility. The obligation to conduct periodic verification of medical devices with a measuring function during their operation is imposed on healthcare institutions (end consumers) and their officials. For violation of this obligation, the guilty persons, namely officials of enterprises and organizations, regardless of ownership, individual entrepreneurs, can be held liable in the form of a fine under Article 172 of the Code of Ukraine on Administrative Offenses [17].

Criminal responsibility. In cases where the failure to conduct periodic verifications of medical devices leads to negative consequences, including a threat to human life and health, criminal liability may arise under Article 367 of the Criminal Code of Ukraine [18] establishes liability for non-compliance or improper execution of official duties, under certain conditions, liability may also arise for the failure to conduct extraordinary verification if it was not carried out before the introduction of the MIs into operation and caused significant damage.

10. Formatting verification results

According to Section IV, Point 2 of Order № 193 [11], the results of the verification of MIs are considered positive if their metrological and technical characteristics comply with the requirements of Law [1] and technical regulations.

Positive results of periodic and extraordinary verifications, as well as verification after repair of MIs, are confirmed by an imprint of the verification seal or by a record with an imprint of the verification seal in the respective section of the operational documents and/or documented in the certificate of verification of the MI.

11. Conclusions

Medical devices with a measuring function are subject to regulations in the field of metrology and metrological activities. Medical devices were excluded from Technical Regulation № 94 [6], but the manufacturer must ensure and declare the accuracy of measurements, quality, and compliance with requirements at the time of circulation and use.

Primary verification was discontinued in 2019, but extraordinary verification is conducted at the request of the applicant or upon reintroduction into use after storage. All other types of verifications are applied to medical devices in operation, including periodic verification, which should be conducted annually for most medical devices.

Verifications should be conducted by the healthcare facility where the medical device is in use, and non-compliance with these requirements may lead to license revocation, administrative, and criminal liability.
References


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