

## عنوان مقاله:

Why Should We Have a Periodic Safety and Performance Program for Medical Devices

## محل انتشار:

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## خلاصه مقاله:

Nowadays, more than ۱۰,۰۰۰ different types of medical devices can be found in hospitals. These devices used in medical centers and hospitals for monitoring and treatment of patients require periodic safety and performance checking in order to have confidence in their functioning and operation. Physicians need better accurate medical measurements in order to better diagnose diseases, monitor patients and deliver treatments, in this way failure to ensure appropriate measurements will certainly have diverse effects. Safety and performance testing of medical devices in the medical sector is a one of the key factor in improving public health. Acquiring results of some investigations indicate a need for new and severe regulations on periodic performance verifications and medical equipment quality control program especially in high risks instruments. The metrological reliability of four high risk medical devices, Electrosurgical unit, Defibrillator, Syringe pump and Infant incubator in use some hospitals (privates and publics) in one of the province of Iran according to international and national standards was evaluated. Quantitative analysis of Some parameters that impact the safety and performance showed the amount of the obtained results in some equipment are in critical range and have higher values than standard limitations. General electrical safety evaluations for measuring the patient leakage currents and patient auxiliary currents carried out for all of groups, in some cases the amount of leakage currents were over the standard limitations. Acquiring results indicate a need for new and severe regulations on periodic performance verifications and medical equipment quality control program especially in high risk instruments. It is also necessary provide training courses for operating staff in the field of metrology in medicine and what's the critical parameters and how they can get good accuracy results equipment

## کلمات کلیدی:

Metrology, Medical devices, Safety, Performance, Calibration

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