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Original article / research

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Introduction: The performance of Blood Glucose Monitoring System (BGMS) is critical as the information provided by the system guide the patient or health care professional in making treatment decisions. However, besides evaluating accuracy of the BGMS in laboratory setting, it is equally important that the intended users (healthcare professionals and patients) should be able to achieve blood glucose measurements with similar level of high accuracy.

Aim: To assess the performance of EXIMO[®] (Meril Diagnostics Pvt. Ltd., Vapi, Gujarat, India) BGMS as per International Organization for Standardization (ISO) 15197:2013 section 8 user performance criteria.

Materials and Methods: This was a non-randomized and post-marketing study conducted at a tertiary care centre of India. A total of 1005 patients with diabetes themselves performed fingertip blood glucose measurement using EXIMO[®] BGMS. Immediately after capillary blood glucose measurement using the blood glucose monitoring system, venous blood sample from each patient was obtained by a trained technician which was assessed by reference laboratory method- Cobas Integra 400 plus (Roche Instrument Centre, Rotkreuz, Switzerland). All the blood glucose measurements assessed by EXIMO[®] were compared with laboratory results. Performance of the system was assessed as per ISO 15197:2013 criteria using Bland-Altman plot, Parkes-Consensus Error Grid (CEG) and Surveillance Error Grid analyses (SEG).

Results: A total of 1005 patients participated in the study. Average age of the patients was 44.93±14.65 years. Evaluation of capillary fingertip blood glucose measurements demonstrated that 95.82% measurements fulfilled ISO 15197:2013 section 8 user performance criteria. All the results lie within clinically non-critical zones; Zone A (99.47%; n=1000) and Zone B (0.53%; n=05) of the CEG analysis. As per SEG analysis, majority of the results fell within “no-risk” zone (risk score 0 to 0.5; 90.42%).

Conclusion: The result of the study confirmed that intended users are able to obtain accurate glucose measurements when operating EXIMO[®] BGMS, given only the instructions and training materials routinely provided with the system, in clinical practice.

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