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Analysis of the Performance of the CONTOUR® TS Blood Glucose Monitoring System: When Regulatory Performance Criteria Are Met, Should We Have Confidence to Use a Medical Device with All Patients?

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Abstract

The article entitled, *Performance of the CONTOUR® TS Blood Glucose Monitoring System,* by Frank and colleagues in this issue of *Journal of Diabetes Science and Technology,* demonstrates that the CONTOUR® TS glucose meter exceeds current regulatory expectations for glucose meter performance. However, the appropriateness of current regulatory expectations, such as International Organization for Standardization (ISO) 15197:2003, is being reevaluated because of increasing concern regarding the reliability of glucose meters in ambulatory and hospitalized environments. Between 2004 and 2008, 12,673 serious adverse events with glucose meters that met the ISO 15197 expectations were reported in the Food and Drug Administration–Manufacturer and User Facility Device Experience surveillance database. Should different glucose meter performance criteria be applied to ambulatory versus critical care patients?

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Abbreviations: (CLSI) Clinical Laboratory Standards Institute, (FDA) Food and Drug Administration, (ISO) International Organization for Standardization, (MAUDE) Manufacturer and User Facility Device Experience

Keywords: assisted-monitoring blood glucose devices, ISO 15197:2003 accuracy performance expectations, MAUDE surveillance system database, self-monitoring blood glucose devices

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