

## New Guideline Supports the Development and Evaluation of Continuous Interstitial Glucose Monitoring Devices

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### Abstract

For the millions of patients who are managing diabetes, daily self-monitoring of blood glucose is a fact of life. However, the cost and inconvenience of self-monitoring have led to noncompliance by many patients. Continuous interstitial glucose monitoring (CGM) has emerged as a promising and welcome alternative to traditional glucose monitoring, which requires the patient to endure repeated finger sticks. The Clinical and Laboratory Standards Institute (CLSI) (Wayne, PA) has been working cooperatively with the Diabetes Technology Society on the development of a consensus guideline for CGM. CLSI has recently released document POCT5-P—*Performance Metrics for Continuous Interstitial Glucose Monitoring; Proposed Guideline*. This document specifies requirements and recommendations for methods determining analytical and clinical metrics of CGM. This guideline will support and streamline the further development and evaluation of CGM devices.

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**Abbreviations:** (CGM) continuous interstitial glucose monitoring, (CLSI) Clinical and Laboratory Standards Institute, (FDA) Food and Drug Administration, (SMBG) self-monitoring of blood glucose

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