



# POCT05

## Performance Metrics for Continuous Interstitial Glucose Monitoring

This guideline provides consensus guidelines for health care professionals, *in vitro* diagnostic and medical device manufacturers, and regulatory agencies regarding the use of continuous glucose monitoring (CGM) systems and data obtained from CGM systems. This guideline covers how CGM data should be assessed for accuracy, how CGM systems should be assessed for factors that can decrease accuracy, and how CGMs should be operated for optimal performance.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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### Abstract

Clinical and Laboratory Standards Institute guideline POCT05—*Performance Metrics for Continuous Interstitial Glucose Monitoring* provides consensus information for health care professionals, *in vitro* diagnostic and medical device manufacturers, and regulatory agencies regarding how continuous glucose monitoring (CGM) data should be assessed for accuracy, how CGM systems should be assessed for factors that can decrease accuracy, and how CGMs should be operated for optimal performance. This guideline defines and explores multiple aspects of CGM performance, including use cases, point and trend accuracy, evaluation of threshold alerts, system stability and reliability, clinical studies for assessing CGM performance, calibration, measurement traceability, and special considerations such as shelf life, cybersecurity, and product labeling.

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## Foreword

Continuous glucose monitoring (CGM) systems are medical devices that measure glucose in the interstitial fluid just under the skin and use algorithms to predict blood glucose values from the measurement. This guideline applies to such devices; however, similar concepts might be applicable to noninvasive or minimally invasive devices. This guideline covers how CGM data should be assessed for accuracy, how CGM systems should be assessed for factors that can decrease accuracy, and how CGM systems should be operated for optimal performance.

The CGM market is experiencing strong growth as accuracy, convenience, sensor duration, and data management capabilities improve and as patients, health care professionals, and payers see the benefits that these devices can provide in the management of glucose levels. Many clinical trials comparing CGM with other blood glucose monitoring methods have demonstrated decreases in mean glycemia, glycemic variability, and the incidence of hypoglycemia. Optimal CGM system performance, as well as practical data comparisons between sensors, can be obtained by following the technical specifications presented in this guideline.

**NOTE:** To facilitate the readability of this guideline, mg/dL is used as the unit of measure. This preference does not constitute a recommendation for mg/dL over mmol/L. If needed, the following formula can be used to convert mg/dL to mmol/L.

$$\text{mmol/L} = \frac{\text{mg/dL}}{18} \quad (1)$$

## Overview of Changes

This guideline replaces the previous edition of the approved guideline, POCT05-A, published in 2008. Several changes were made in this edition, including:

- Extensively revising every chapter
- Adding new chapters that discuss:
  - CGM device use cases
  - Cybersecurity for CGM devices
  - CGM device labeling
- Rearranging subchapters and appendixes, including:
  - Changing stand-alone chapter on lag time to become part of Chapter 8
  - Including text describing establishing measurement traceability in Chapter 4
  - Replacing appendix on clinical studies with Chapter 9
  - Replacing appendix on rate deviation with Subchapters 6.3.1, 6.3.2, and 6.4
- Eliminating appendix covering continuous glucose-error grid analysis

**NOTE:** The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

### Key Words

Accuracy, bias, calibration, continuous, diabetes, glucose, lag, metrics, monitoring, sensor, stability, trueness

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# Performance Metrics for Continuous Interstitial Glucose Monitoring

## Chapter 1: Introduction

This chapter includes:

- Guideline’s scope and applicable exclusions
- Background information pertinent to the guideline’s content
- Standard precautions information
- Terminology information, including:
  - Terms and definitions used in the guideline
  - Abbreviations and acronyms used in the guideline

### 1.1 Scope

This guideline provides recommendations for methods used to determine analytical and clinical metrics of continuous glucose monitoring (CGM) as an indicator of blood glucose values. It discusses use cases, point accuracy, trend accuracy, evaluation of threshold alerts, system stability and reliability, clinical studies for assessing CGM performance, calibration, traceability of measurement, cybersecurity, and device labeling.

The intended users of this guideline are *in vitro* diagnostic and medical device manufacturers, regulatory agencies, and health care professionals. This guideline is not intended for use by patients and does not discuss devices that do not meet the definitions of continuous, interstitial, and glucose monitoring.

### 1.2 Background

The use of self-monitoring of blood glucose (SMBG) devices or glucose meters has led to more normal glucose levels and lower risk of cardiovascular and long-term complications in both type 1 and type 2 diabetes. Patients typically use SMBG devices to test blood glucose levels several times a day to plan diet and/or exercise, to manage diabetes medications, including insulin dosages, and to correct abnormal blood glucose values. Although these devices are easier to use than in the past, many diabetes patients do not comply with SMBG testing at the frequency recommended by their physician because of the cost of testing supplies, the pain of repeated SMBG measurements, the environmental drawbacks of blood and sharps waste, and the overall inconvenience of monitoring.