



IS/ISO 15197 : 2013 - In vitro Diagnostic Test Systems - Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus

This standard defines a **blood-glucose monitoring system** designed for self-testing by individuals with diabetes mellitus. It assists users in monitoring their blood-glucose levels, helping them manage their condition and minimize health complications.

Users expect the system to be accurate, reliable, and user-friendly, delivering consistent readings that can be trusted. Key factors include accuracy across a range of glucose levels, repeatability, and durability under various conditions (such as differing temperatures and humidity levels). Usability features like display clarity and device handling are also essential.

The standard sets rigorous accuracy and reliability criteria, detailing protocols for precision and performance testing to ensure measurements are within acceptable limits across glucose concentration ranges. It mandates safety features, such as shock protection and mechanical resistance, and establishes testing protocols for durability to meet varied environmental conditions. Usability guidelines ensure the device is easy for self-testing, with display, handling, and performance expectations tailored to consumer needs. The standard, through these specifications, aims to align with consumer expectations of a safe, accurate, and durable monitoring tool.