IS/ISO 15197: 2003

Indian Standard

IN VITRO DIAGNOSTIC TEST SYSTEMS REQUIREMENTS FOR BLOOD-GLUCOSE MONITORING SYSTEMS FOR SELF-TESTING IN MANAGING DIABETES MELLITUS

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 15197: 2003 *'In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Surgical Disposables and Dressings Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Blood-glucose monitoring systems are *in vitro* diagnostic medical devices used predominantly by individuals affected by diabetes mellitus. Diabetes mellitus is caused by a relative or absolute deficiency in insulin secretion or by insulin resistance leading to abnormal concentrations of glucose in the blood, which may result in acute and chronic health complications. When used properly a glucose monitoring system allows the user to monitor and take action to control the concentration of glucose present in the blood.

This standard is intended for blood-glucose monitoring systems used by laypersons. The primary objectives are to establish requirements that result in acceptable performance and to specify procedures for demonstrating conformance to this standard.

Performance criteria for blood-glucose monitoring systems were established from the accuracy (precision and trueness) required for individual glucose results. System accuracy criteria, also known in the *in vitro* diagnostics (IVD) industry as total error criteria *[see*NeClS EP 21-P(35)], are used in this standard because some of the metrological terms commonly used in this standard (for example, uncertainty) would not 'be familiar to lay users. System accuracy, which is affected by systematic bias and measurement uncertainty, describes the degree to which individual results produced by a glucose monitoring system agree with the true glucose values when the system is used as intended by laypersons.

The criteria for system accuracy are based on three considerations:

a) The effectiveness of current technology for monitoring patients with diabetes mellitus, as Demonstrated in clinical outcome studies using state-of-the-art monitoring devices;
b) Recommendations of diabetes researchers as well as existing product standards and regulatory guidelines; and
c) The state-of-the-art of currently available technology, as evidenced by the performance of existing commercial products.

In arriving at the performance criteria, desirable goals has to be weighed against the capabilities of existing devices (the current state-of-the-art) and their effectiveness in clinical outcome studies. It was decided that overly demanding performance requirements would cause manufacturers to focus design improvements on analytical performance at the expense of other important attributes. For example frequency of testing by diabetic patients can be as important as the accuracy of an individual result, and greater convenience of glucose self-testing improves patient compliance. The system accuracy criteria define the minimum acceptable performance of a blood-glucose measuring device intended for self-monitoring.

Future advances in technology are expected, which should result in improved performance of glucose monitoring devices. Such performance improvements will be driven by the competitive marketplace, particularly through reduction of dependence on user technique.

Requirements that are unique to self-monitoring devices for blood-glucose, including the content of information supplied by the manufacturer, are addressed in this standard. General requirements that apply to all *in vitro* diagnostic medical devices and are covered by other standards (for example, IS 15579 and ISO 14971) are incorporated by reference where appropriate.

Although this standard does not apply to measurement procedures with results on an ordinal scale (for example, visual, semi-quantitative measurement procedures), it may be useful as a guide for developing procedures to evaluate the performance of such systems.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

. a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker in the International Standard while in Indian Standards the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to the following International Standard for which Indian Standard also exists. The corresponding Indian Standard which is to be substituted in its place is listed below along with its degree of equivalence for the edition indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 13485 : 2003 Medical devices Quality management systems Requirements for regulatory purposes	IS 15579 : 2005 Medical devices- Quality management systems- Requirements for regulatory purposes	Identical

International/Other Standard	*Title*
ISO 14971 : 2007	Medical devices - Application of risk management to medical devices
ISO 17511 : 2003	*In vitro* diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and controlled materials
IEC 60068-2-64 : 1993	Environmental testing - Part 2: Test methods - Test Fh: Vibration, broadband random (digital control) and guidance
IEC 61010-1 : 2001	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
IEC 61010-2-101 : 2002	Safety requirements for electrical equipment for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment
IEC 61000-4-2 : 2008	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
IEC 61000-4-3: 2006	Electromagnetic compatibility (EMC) - Part 4-3:Testing and measurement techniques - Radiated, radio-frequency electromagnetic field immunity test
IEC 61326: 2002	Electrical equipment for measurement, control and laboratory use – EMC requirements

EN 376 : 2002	Information supplied by the manufactures with *in vitro* diagnostic reagents for self-testing
EN 13612: 2002	Performance evaluation of *in vitro* diagnostic medical devices
EN 13640 : 2002	Stability testing of *in vitro* diagnostic reagents

The Standard also makes a reference to the SIS certification marking of the product. Details of which is given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values *(revised)'.* The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

1 Scope

This International Standard specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples and procedures for the verification and the validation of performance by the intended users. These systems are intended for self-testing by laypersons for management of diabetes mellitus.

This International Standard is applicable to manufacturers of such systems and those other organizations (e.g. requlatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.

This International Standard does not

-provide a comprehensive evaluation of all possible factors that could affect the performance of these systems,

-pertain to glucose concentration measurement for the purpose of *diagnosing* diabetes mellitus,

-address the medical aspects of diabetes mellitus management, or

-apply to measurement procedures with results on an ordinal scale (e.g. visual, semiquantitative test methods).