RESEARCH PAPER

Quality and Regulation Standards for Blood Glucose Meters as Medical Devices in India

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ABSTRACT

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Introduction

A glucometer, commonly called a blood glucose monitor, is a device that can be used in the home setting or by health professionals to measure the glucose concentration in the blood. It comprises a portable meter and test strips that allow you to quantify the glucose in a drop of blood. Blood glucose monitoring devices are crucial for people with diabetes as they allow them to keep track of their blood sugar levels regularly[1]. Diabetes Control and Complications Trial along with the Epidemiology of Diabetes Interventions and Complications studies have proven that having good glucose control through the use of home monitors was associated with less disease complications in diabetes patients[2].

Regulatory Framework for Blood Glucose Monitors in India

In India, blood glucose meters (BGMs) are classified as medical devices and are regulated by the Central Drugs Standard Control Organization (CDSCO), the national regulatory body for drugs and medical devices. A blood glucose meter is an in vitro diagnostic (IVD) device designed to measure glucose levels in the blood. CDSCO is India's national regulatory body for medical devices, in vitro diagnostics (IVD) and drugs. In India, many medical devices must be licensed by CDSCO. Manufacturing of medical devices such as blood pressure monitors in India requires a manufacturing license from CDSCO. The Medical Devices Act, 2017 and other standards set by the Bureau of Indian Standards require all such devices to be registered and meet the requirements (BIS).

As ISO 13485 certified consultants, we provide training to manufacturers and implement quality control procedures as per the required standards to obtain a manufacturing license. If the manufacturer is not from India, then you need to choose an IAA (Indian Authorized Representative). Once the manufacturers complete the documentation process, they will be licensed to manufacture, import or export blood glucose meters. CDSCO is responsible for the approval, inspection and regulation of medical devices in India. Products like BGM must go through an approval process before they can be sold in stores[3].

Manufacturers are required to submit an application for clearance to CDSCO, which includes information on the safety, performance and quality of the equipment. The "Medical Devices Regulations (2017)" came into force on January 1, 2018, and classifies medical devices as Class A, Class B, Class C and Class D based on their risks. Most blood glucose meters are classified as Class B (low to medium risk). Manufacturers are also required to demonstrate that their devices meet the safety and performance standards required by Indian regulations before receiving marketing approval[4].

Quality Standards for Blood Glucose Monitors in India

To ensure the accuracy and reliability of blood pressure monitors, quality is essential. Accuracy criteria are based on three considerations:

a) The effectiveness of current devices for monitoring diabetes patients, as demonstrated by clinical studies using state-of-the-art diagnostic tools;
b) Recommendations from diabetes researchers, 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[5,6].

The standards and certifications governing these devices include:

ISO 15197:2013 (In-vitro Diagnostic Test Systems - Requirements for Blood Glucose Monitoring Systems): The basic international standard for blood glucose measuring systems. It outlines the performance and accuracy requirements that must be met for the operation of a blood glucose meter.

Accuracy: A blood glucose meter must provide some accuracy in blood glucose testing. According to ISO 15197:2013, the accuracy of the blood glucose measurement must be within ±15% for blood glucose levels above 75 mg/dL and ±0.15 mg/dL for values below 75 mg/dL.Interference Testing: The meters are tested to ensure they are not affected by common substances found in blood, such as certain medications.

Calibration and Performance: The equipment used must be calibrated to give consistent results under different conditions (such as temperature and humidity) and to provide stable readings over time.

Indian Standards (IS 13450): Blood pressure monitors sold in India are generally required to comply with IS 13450, an Indian standard that follows international standards to ensure the quality and accuracy of the devices. Manufacturers frequently undergo testing to ensure that their equipment meets BIS standards, which may include:

a) Performance evaluation
b) Safety testing
c) Calibration and accuracy checks

Bureau of Indian Standards (BIS): In India, the Bureau of Indian Standards (BIS) is responsible for certifying the quality of medical devices, including blood glucose meters. These devices must meet quality control and specific testing requirements to qualify for BIS certification. BIS certification ensures that the equipment is safe and effective for use in India.

Clinical Validation: Clinical trials or field studies have been conducted to verify the real-world accuracy of blood glucose meters. The results of these studies must be submitted to CDSCO as part of the approval process.

Post-Market Surveillance: Once a blood glucose meter is approved for commercial use, manufacturers must conduct post-market surveillance to ensure that the device continues to meet safety and security standards:

a) Manufacturers are required to monitor the performance of a device once it is commercially available and report any adverse events to CDSCO.
b) If the device is found to be problematic or dangerous after release, initiate a recall.

Recent Developments & Challenges in India

1. **Regulatory Harmonization:** India is working to improve healthcare regulations with international standards to improve the quality of healthcare and facilitate access to safe medical equipment.
2. **R&D and Innovation:** Innovations in blood glucose meters continue to increase, such as the development of non-invasive blood glucose meters. Regulators in India are adapting their structures to accommodate new technologies.

Challenges in Compliance: Smaller manufacturers sometimes face challenges in meeting the stringent regulatory and quality standards, leading to delays in product approval and market entry.

Quality checks as per WHO: The WHO technical specification for blood glucose meter was developed by WHO in collaboration with a working group of experts. Major specifications as per WHO as follows:

Performance Characteristics		
1	Accuracy	Analytical performance shall remain stable throughout the measurement of the analyte. The assay shall be linear across the entire measuring interval available. External Quality Assurance (EQA)

		at regular intervals is advisable for devices in healthcare settings (EQA watery controls only should not be preferred).
2	Range of Measurement and related Accuracy	Measurement range not less than from 30 to 400 mg/dL (1.7 to 22.2 mmol/L), preferably from 20 up to 500 mg/dL (1.1 to 27,8 mmol/L). Accuracy must meet ISO-15197 standard, in particular: a) 95% of blood glucose results must be within 15% for values equal to or greater than 100 mg/dL, and 15 mg/dL for values below 100 mg/dL. b) 99% of results to fall within zones A or B of the Consensus Error Grid (Parkes error grid)
3	Analytical specificity	Analytical specificity (interferences): method shall be evaluated and demonstrate no interference from ascorbate, lipid, protein, high/low hematocrit. At least the
		interference list of ISO 15197:2013 shall be evaluated and demonstrated.
4	Limit of detection	Not higher than 30 mg/dL or 1.7 mmol/L (better not higher than 20 mg/dL or 1.1 mmol/L)
5	Invalid/error/unreturnable rate	Test failure, low battery, test strips problems (i.e. expired or inserted wrong side) and malfunction messages should also be available. Error messages linked to the specific linearity range (when available).
6	Precision (repeatibility/reproducibility)	Repeatability (within-run variability) CV <5.0 %. Must be stated in instructions for use.
7	Trueness of measurement: bias	Typically <15% (better 10%) from target value or less than 0.83 mmol/L for lower glucose ranges, hematocrit levels will significantly affect result (bias) (see "Test Limitations" requirement for details).
Technical And Operational Characteristics		
1	Principle of the assay	Enzymatic method (or equivalent; equivalence shall

		be demonstrated and clearly reported based on the standards required), commonly either glucose oxidase or glucose dehydrogenase, with photometric, amperometric, elecrochemical or biosensor detection
2	Specimen(s) stability	Specimen shall be stable for at least 15 minutes (better for at least 30 minutes) from the time to the exposure to enviroment conditions. In case of venous blood samples are used, any specific need of anti-coagulants use should be clearly stated and detailed by the manufacturer.
3	Specimen(s) volume	Sample volume at least < 15µl (in case of self-monitoring/single patient device: better if < 10µl). Manufacturer instructions for tubes and/or specific analytical instruments shall state additional requirements, if any.
4	Type of result	In case of POCT/multiple patients device for professionals: quantitative values shall be clearly presented in display and in mmol/L or mg/dL (or both, when available, depending on manufacturer settings). In case of self-monitoring/single patient device: it should not be possible to switch between different units
5	Time to result	In case of POCT/multiple patients device for professionals: results available in less than 1 minute (preferably less than 30 seconds). In case of self-monitoring/single patient device: results available in less than 30 seconds (preferable less than 10 seconds).
6	End-point stability	Not applicable
7	Ease of use for POC tests only: number of steps that require precision	Single step, easy to use devices.
8	Specimen throughput per operator, per hour, per 8-hour working day or per batched run	In case of POCT/multiple patients device for professionals: not less than 50 specimens per 8-hour working day, depending on

		healthcare setting.
9	Test limitations	Haematocrit acceptable range at least from 30% to 55% (better from 15% up to 65%). Device able to compensate for high haematocrit value. The manufacturer shall state ALL additional limitations, if any (i.e. blood concentrations of ascorbic acid or galactose, etc.)
10	Internal quality control	Quality control features available. Quality Control material shall be run as defined by the manufacturer. In case of self-monitoring/single patient device: automatic meter calibration check (no "coding"). In case of POCT/multiple patients device for professionals: preferably automatic meter calibration check (no "coding") and/or calibration checks frequency and related activities clearly stated by the manufacturer (at least twice per year would be recommended).
11	Compatability with external quality control material	External Quality Assessment (EQA) material shall be run from a National EQA provider (when available).
12	Transport stability of kit/reagents (temperature and humidity)	At least in the range from 5°C to 35°C (better if up to at least 40°C), protected against high humidity and direct sunlight. Manufacturers instructions shall state specific detail and limitations, if any.
13	Storage stability of kit/reagents (temperature and humidity)	At least in the range from 5°C to 35°C (better if up to at least 40°C), protected against high humidity and direct sunlight. Manufacturers instructions shall state specific detail and limitations, if any.
14	Shelf-life of kit/reagents upon manufacture (months)	All strips should have at least 12 months expiry date (better 18 months) from the date of production (better: from the date of supply). Shelf life for reagents shall be anyway clearly stated by the manufacturer.
15	Remaining shelf-life of kit/reagents upon delivery (months)	Strips should have a minimum of 2 (better 3 or more) months shelf life

		after opening the strip vial.
Instrument Physical And Technical Characteristics		
1	Size of device (Height x Width x Depth)	Handheld device (approx. average size as reference: 6 cm x 12 cm x 3 cm)
2	Weight of the device (kg)	Not greater than 0.5 kg (preferably including batteries)
3	Power requirements and characteristics	Operated by internal battery with not any memory loss if batteries are removed. Batteries may be single use, or rechargeable (preferred) with external AC battery charger, or by USB connection. Power requirement 100-240 V (± 10%)/ 50-60Hz (country dependant) for rechargeable devices. Charger, if used, must have protection against over-voltage and over-current line conditions. If rechargeable device is provided, operation should be preferably possible while charging. Battery should be replaceable without using any tools. Preferable: due to trasnport restrictions, the compatible batteries provided should be without Lithium
4	Time to battery charge	Not higher than 3 hours
5	Battery duration	In case of POCT/multiple patients device for professionals: not less than up to 30 days at an average of 20 tests per day and/or 600 tests in total (better: avereage of 30 tests per day and/or 900 tests in total). In case of self-monitoring/single patient device: not less than 100 tests.
6	Alternative charging options	Solar
7	Operating and storage conditions (temperature and humidity)	Glucometer: operating temperature range at least: 10°C - 40°C (better at least: 5°C - 45°C), humidity: 10-80% (better up to 90%) without condensation, and atmospheric pressure operating range: at least from 800 up to 1060hPa; additional altitude related operating

		limitations, up to at least 3000m, should be clearly stated by the manufacturer. Storage conditions range: at least -5°C - 50°C (better at least: -10°C - 55°C) and humidity 20 % – 80% RH. Test Strips packages: for high humidity (> 80%) or temperature conditions (> 40°C), the manufacturer shall guarantee that the container for strips, when provided, can be opened frequently without influencing the performance of strips/glucosemeter.
8	User interface	LCD display, simple test menu. In case of POCT/multiple patients device for professionals: option for connection to laboratory computer and middleware should be also available. In case of self-monitoring/single patient device: technical solutions to improve the readability for private users with limited visual capacity should be preferably available.
9	Displayed parameters	Digital display of test results. Electronic output. Audible and/or visual alert/alarm indicator at least for "low battery", "malfunction" and/or "strips error". Preferable: "expired strip" messages/alarm when a strip used is expired and additional alarm/warning for elevated or too low glucose levels
10	Display languages	At least 20 languages should be available including Arabic, Chinese, English, French, Russian and Spanish. Local language of the Country of sales would be also preferred, when available.
11	Built-in memory storage capacity	In case of POCT/multiple patients device for professionals: storage for at least 300 test results and 10 control results (better up to at least 500 test results and 20 control results). In case of self-monitoring/single

		patient device: storage for at least 100 test results (better up to at least 250 test-results for long term-storage) and, when available, 5 control results.
12	Diagnostic connectivity	Capabilities for data transmission and storage e.g. via USB, bluetooth, cable. In case of self-monitoring/single patient device: electronic linkage to manufacturer for data updates and/or instrument monitoring should be also preferably available. In case of POCT/multiple patients device for professionals: Availability of a digital connection to the Electronic Patient Record AND/OR data connectivity compatible with laboratory information system (LIS) and programme database to enable information sharing. Electronic linkage to manufacturer for data updates and instrument monitoring should be also preferably available.
13	Open or Closed system	Preferably open (able to use compatible consumables of different brands)

Conclusion

India's regulation of blood glucose monitors involves a complex blend of global standards (like ISO 15197:2013) and local regulations under CDSCO and BIS. These make certain that glucose meters meet rigorous safety and accuracy standards before reaching the market. In India, CDSCO regulates handful devices through gazette notifications. These devices are called notified devices. A few products are classified as drugs in India but are classified as devices in other countries. This system is not in consonance with international standards. Existent system appears to be basic in nature when compared to regulatory systems of USA and EU. Therefore, revamping of existing regulatory system is required for administration of devices moving in commerce and creating harmonized standards of blood glucose monitors.

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