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Changes to the ISO 15197: 2013 Standard – Urgent Action Required

A revised set of quality standards for blood glucose monitoring was published in May 2013 to help ensure accuracy and consistency of results for people with diabetes[1].

The transition period for the implementation of these standards will end in **May 2016**. As a result, **test strips may be unavailable** for non-compliant meter systems. It is vital that healthcare professionals (HCPs) ensure their patients are upgraded to **compliant meter systems** before this date.

A significant number of patients are currently on non-ISO 15197: 2013 compliant meter systems, and therefore will need to be changed (up to a third of patients).

To assist HCPs, BIVDA has produced the following briefing which outlines the changes to the Standard and what can be done to help ensure a smooth transition.

How has the ISO 15197 standard changed?

The requirements for meter systems are set by the International Organization for Standardization (ISO) and ensure that they are of a suitable standard. The first ISO standard for meter systems was published in 2003 and the latest standards reflect recent advances in technology.

The requirements of the ISO 15197: 2013 Standard must be met in order for a meter system to become CE certified compliant. Among the changes to the Standard include the four revised criteria referenced below:

1. Higher stringency for minimum accuracy criteria
    - 3 different lots of strips must now be evaluated and reported individually and combined
    - 99% of results must fall within zones A+B of the Consensus Error Grid (CEG) for T1
    - 95% of results >5.5mmol/L must fall within 15% of the reference method
    - 95% of results <5.5mmol/L must fall within +0.83mmol/L of the reference method
    - Scatter plots must be produced
2. User performance evaluation: A full performance study with lay persons must be conducted and reported
3. Haematocrit study: The effect of HCT/PCV must be determined and inserted in the pack insert if falling outside the criteria
4. Chemical interference: Updated chemicals and values must be analysed and reported

[1] International Organization for Standardization. In vitro diagnostic test systems – requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. ISO International Standard 15197:2013.

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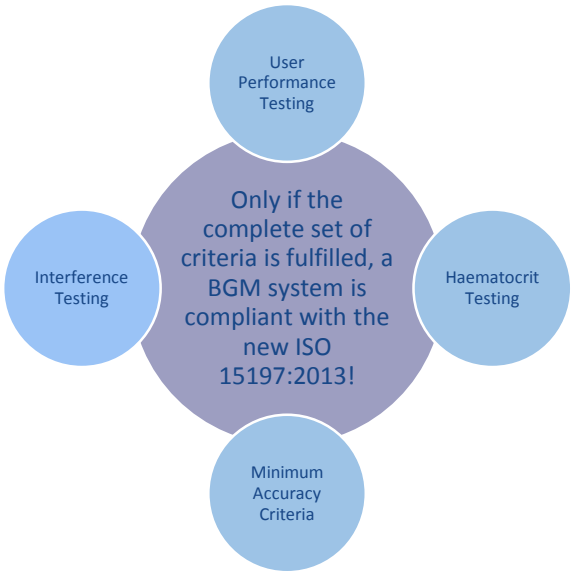
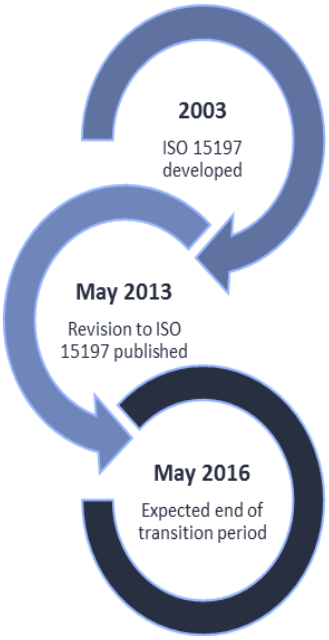


What do the changes mean for healthcare professionals?

The revised ISO 15197: 2013 standard will change which meter systems HCPs can recommend to patients due to test strips becoming unavailable over time for meter systems that do not meet the revised ISO 15197: 2013 criteria.

Upgrading to fully compliant meter systems now minimises the resources spent on helping patients and staff through the transition. Advice concerning the upgrade can be integrated into routine check-ups or new patient assessments.



Next Steps

To establish if a meter system is compliant, HCPs should check the current meter system's packaging insert or consult the website or customer care line of the relevant manufacturer.

HCPs should then check that their patients are using ISO 15197: 2013 Standard compliant meter systems and if they are not, upgrade them.

For further information, the ISO 15197: 2013 Standard can be obtained at the following link:

http://www.iso.org/iso/catalogue_detail?csnumber=54976

Contact Us

If you have any questions about the information in this briefing, please contact us at enquiries@bivda.co.uk.

The British In Vitro Diagnostics Association (BIVDA) represents over 100 manufacturers and suppliers of in vitro diagnostics (IVD) tests, ranging from British start-up companies to UK subsidiaries of multinational corporations.