

12 APR 2016

Dr Suzy Lishman  
President  
Royal College of Pathologists  
21 Prescot Street (4<sup>th</sup> Floor)  
London  
E1 8BB

30 March 2016

Dear Suzy,

### Changes to the ISO 15197: 2013 Standard for Blood Glucose Monitoring

On behalf of the British In Vitro Diagnostics Association (BIVDA), I am writing to you regarding the ISO 15197: 2013 Standard for blood glucose monitoring.

BIVDA is the industry association for manufacturers and suppliers of *in vitro* diagnostic (IVD) tests. We currently represent over 100 members from the IVD industry, ranging from British start-up companies to UK subsidiaries of multinational corporations.

A key priority for BIVDA and our Diabetes Working Party is raising awareness among healthcare professionals (HCPs) that the implementation period for the revised ISO 15197: 2013 standard for blood glucose monitoring ends in **May 2016**.

As a result of the updated standard, meter systems must meet new criteria in order to be compliant. It is vital that patients have their meter systems checked and if necessary, upgraded, before May as test strips will become unavailable for non-compliant meter systems.

BIVDA has produced the enclosed briefing to help inform HCPs about the changes and how they will impact patients. We would be grateful if this briefing could be circulated among your members. Should you require an electronic copy, please ask your office to contact BIVDA's External Affairs Manager, Emma Thomas at [emma@bivda.co.uk](mailto:emma@bivda.co.uk).

I hope that you find the briefing useful but should you wish to discuss this further, please do not hesitate to contact me.

Yours sincerely,

Doris-Ann

Doris-Ann Williams MBE  
Chief Executive



## 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.

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).

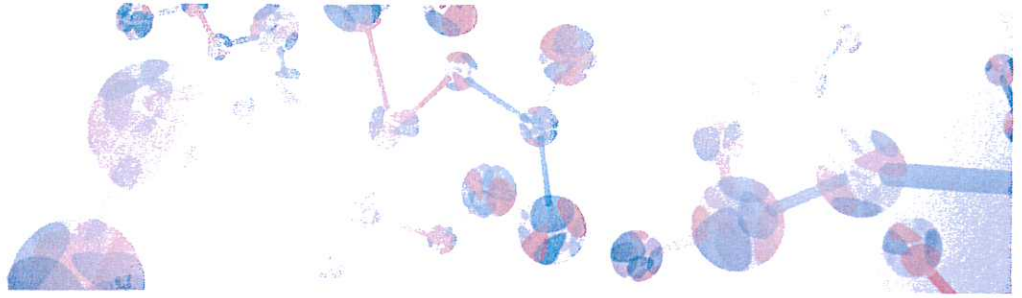
BIVDA has produced the following briefing which outlines how the Standard has changed and what can be done to help ensure a smooth transition. We would be grateful if you could share this with your members.

### **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



### 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 meters 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

We would encourage the Royal College of Pathologists to disseminate this briefing among their members. HCPs should check that their patients who have been diagnosed with diabetes are using ISO Standard 15197: 2013 compliant meter systems and if they are not, upgrade them.

To establish if a meter system is compliant, HCPs should consult the website or customer care line of the relevant manufacturer.

For further information, the ISO 15197: 2013 Standard can be obtained at the following link: [http://www.iso.org/iso/catalogue\\_detail?csnumber=54976](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](mailto:enquiries@bivda.co.uk).

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