

Device Safety Information

Reference: DSI/2025/003

Issued: 22 July 2025

Trinity Biotech Premier Hb9210™ HbA1c Analyser: Risk of Positive Bias and Updates to Instructions for Use (IFU), including use as a diagnostic aid in diabetes mellitus

Device Safety Information (DSI) Placeholder

The above Device Safety Information (DSI) has been published by MHRA and not NHS National Services Scotland (NSS). For this reason it cannot be uploaded to the NSS website. However, you can view it on the MHRA website by [clicking here](#)

MHRA published the (DSI) in partnership with devolved administrations. IRIC has adopted it into the Scottish health and social care system and it should therefore be implemented by all affected health boards, local authorities and independent contractors delivering publicly funded health and social care services.

A PDF version of the alert has been distributed direct to the Incidents and Alerts Safety Officer (IASO) Network for onward local cascade. All health boards and local authorities in Scotland have a named IASO and you can [find their details here](#).

If you are affected by the above DSI but have not received a copy, we recommend you contact your local IASO as soon as possible. This is important to ensure you are not missed from future alert distributions on the same or similar subject matter.

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure NHS National Services Scotland, Tel: 0131 275 7575, email: nss.irc@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in [DL\(2024\)32](#), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities*, issued 16 December 2024.

To find safety alerts:
scan the QR code or [click this link to visit our website](#)



To report an incident:
scan the QR code or [click this link to visit our website](#)



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