



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: FOI 2024/00683

27 November 2024

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 5 November. You wrote:

Can I please make a Freedom of Information request for suspected problems - also known as "adverse incidents - "with a piece of equipment reported to the MHRA.

I understand at least nine laboratories have reported issues with the Premier Hb9210(tm) HbA1c Analyzer, made by Trinity Biotech. A field safety notice was issued on 30th September 2024.

Can I please request:

- * The names of each of laboratories and organisations that run them that have reported an issue with the above piece of equipment to the MHRA*
- * The month and year of each report*
- * Brief details of the problems contained in the report*

MHRA Response

We can confirm that the Agency holds the information you are seeking.

Request 1:

We are engaging an exemption from disclosure under Section 41(1) of the FoI Act, which protects information provided in confidence.

The information you have requested relates to the names of organisations which submitted specific adverse incident reports. This information was obtained by the Agency from the reporting individual and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information.

Request 2:

I can confirm that the MHRA has received 5 UK adverse incident reports associated with the Premier Hb9210(tm) HbA1c Analyzer, 4 of which are related to the FSN published in September 2024. It is important to note that some of the adverse incidents mentioned in the FSN will have been reported directly to the manufacturer who must then consider whether they meet the criteria for submission to the MHRA. Further information regarding adverse incident reporting is available at: <https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance>.

Please find Table 1 below which displays further information on all the adverse incident reports received by the MHRA for the Premier Hb9210(tm) HbA1c Analyzer including the International Medical Device Regulators Forum (IMDRF) Annex A (Medical Device Problem) terms reported and month and year of receipt.

Table 1: Adverse incident reports relating to Premier Hb9210(tm) HbA1c Analyzer and reported IMDRF Annex A codes, received from start of Yellow Card Scheme – 18/11/2024

Report	Month received by MHRA	Year received by MHRA	IMDRF Annex A codes reported
1	June	2021	A0908-Incorrect, Inadequate or Imprecise Result or Readings
2*	August	2024	A0203-Defective Device
			A0709-Device Sensing Problem
3*	September	2024	A0908-Incorrect, Inadequate or Imprecise Result or Readings
4*	September	2024	A0908-Incorrect, Inadequate or Imprecise Result or Readings
5*	September	2024	A0803-Imprecision

*Related to FSN issued in September 2024

When considering the data provided within this response, please consider the below information:

- Inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. Additionally, it is important to note that the number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the delivery device is known.
- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues or multiple events in the same report.
- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of device and on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate.
- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with

any particular device.

- The numbers may include reports where the incident has been taken from published literature or the report may be about notification of a safety communication.
- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details at a later date.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

Re-use of our information

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>