Medicines & Healthcare products
Regulatory Agency

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Mr R. Brittain
Assistant Coroner for Inner London North

[redacted]

12 September 2025

Dear Mr Brittain,

Regulation 28 Report into the death of Sybil Morgan-Gray

We acknowledge your Regulation 28 Report relating to the death of Ms Sybil Morgan-Gray, which was received by the Medicines and Healthcare products Regulatory Agency (MHRA) on 8th May 2025. [redacted], the Chief Executive Officer of the MHRA has asked me to respond on his behalf given my role as Chief Safety Officer at the MHRA.

We would like to thank you for your help in providing the additional information requested in relation to the manufacturer and your understanding that this has delayed the response beyond the original requested timelines. We would like to offer our sincere condolences to Ms Sybil Morgan-Gray's family on their tragic loss.

The MHRA is an executive agency of the Department of Health and Social Care ("DHSC") and is responsible for the regulation of all medicines and medical devices marketed in the UK. Patient safety is our top priority, and we carefully consider the findings of all Prevention of Future Death reports.

Your report identified a concern regarding the interpretation of blood gas machine readings. Specifically, when blood glucose levels are unrecordably low, the machines report this as '- - -↓'. Your concern was that this display can be misinterpreted as indicating the sample is unanalysable, rather than accurately reflecting an extremely low glucose level, which could lead to delayed or inappropriate clinical responses, potentially resulting in future deaths. Your report notes that it was unclear why the results are not recorded as 'Low' or similar.

All *in vitro* diagnostic devices have two standard assay ranges, a 'detectable' range, and a 'reportable' range. The detectable range is the range of analyte concentrations that the

device can detect while the reportable range is the analytical range that demonstrates a suitable level of accuracy and precision to be reported. Therefore, any analyte measurement that falls outside either of these ranges should be repeated to determine the cause of the result, which could be that the concentration was too low or that there was a problem with the sample that meant it could not be analysed.

Because of the multiple ranges within any given assay, it is usually not possible to use generic terms such as ‘low’ or ‘high’ as these may lead to confusion as to which range the result is referring to. Therefore, it is common for manufacturers to include in the results different symbols that reflect which range the result sits outside. The symbols or alerts should be clearly defined in the manufacturer’s Instructions for Use guidance and subsequently incorporated into any third-party Standard Operating Procedures (SOP) or training material.

The Siemens RAPIDPoint 500 System Operator’s Guide contains the following table in section 2-32:

Understanding Result Symbols

The following symbols identify results that are out of range or that need your attention. These symbols and results appear in red on the screen. They also appear on the report. The patient ranges can appear on the printed report, if this option is selected in Setup.

Symbol	Description
↑	The result is above the patient range.
↓	The result is below the patient range.
-----↑	The result is above the reporting range.
-----↓	The result is below the reporting range.
-----?	The system has an atypical response when measuring this parameter and cannot report the result. Analyze the sample again, if possible.
?	The reported result is questionable. The system has been set to use Analytical Range limits and the Display Question Result options, which should not be selected at the same time. Ensure Analytical Range limits, Display Question Result, or both are turned off, and analyze the sample again. The ? symbol displays without a value in the patient list at the **Recall** screen. The <? and >? symbols display with values in printed reports and the display.
<?	
>?	
>	The result is greater than the selected Analytical Range limit.
<	The result is less than the selected Analytical Range limit.[1]

1. Analytical Range limits do not apply to QC results.

It is therefore important that device users are familiar with any warnings or symbols displayed on the device and the recommended course of action, particularly when results fall outside of the reporting range. We have investigated whether this is a wider issue across all point of care analysers and can confirm that we have not identified any further safety signals reported through our Yellow Card scheme associated with the interpretation of glucose results, or any other point of care results, outside the reporting range.

It is our intention to share applicable details of this report with the manufacturer so that they can review this case as part of their on-going post market surveillance activities, and to work with the trust to resolve any identified training issues that may have arisen. We will also engage with NHS England colleagues to determine if any additional similar cases have been reported to Learn from Patient Safety Events and if there are, will work with NHSE to ensure appropriate training is in place.

We hope this addresses your concerns.

Yours sincerely,

[redacted]

[redacted]
Chief Safety Officer
Medicines and Healthcare products Regulatory Agency
[redacted]