

IMPORTANT PRODUCT NOTICE
GEM PAKs for GEM Premier 5000 with iQM2® and GEM Premier 7000 with iQM3®

July 15, 2026

Dear Valued GEM Premier 5000 and GEM Premier 7000 Customer:

This notification is to inform you of an upcoming optimization to the GEM Premier 5000 and GEM Premier 7000 PAKs affecting the sodium (Na^+) parameter. This PAK optimization will improve harmonization of Na^+ patient results with the literature-based serum reference range in the respective GEM Operator's Manual.

Background on Na^+ Optimization

A review of Na^+ results from normal patient populations on the GEM Premier 5000 and GEM Premier 7000 systems shows a negative bias relative to the published serum reference range. To optimize alignment with this reference range, Werfen will implement an adjustment to the Na^+ setting in future PAK lots. This adjustment applies a shift of approximately +3 mM across the Na^+ analytical measurement range.

Note: Optimized PAKs are expected to begin shipping as of September 14th, 2026. These optimized PAKs will include a sticker on both the PAK box and foil packaging, as well as an informational card advising users of the Na^+ setting adjustment.

This optimization applies to future PAK lots only and does not require removal or correction of PAKs currently in use.

This PAK optimization:

- Does not change the test methodology
- Does not change reported units
- Does not change labeled performance claims
- Does not affect quality control (QC), external quality assessment, or National Institute for Standards and Technology (NIST) traceability
- Does not affect system safety or reliability

Risk Impact of Na^+ Optimization

As a feature, the GEM Premier 5000 and GEM Premier 7000 systems allow users to apply custom correlation coefficients to measured parameters to better align results with other devices used in their workflow.

- For customers **without** applied custom Na^+ correlation coefficients, no impact is expected beyond optimized alignment of normal patient Na^+ results to the published serum reference range.



Risk Impact of Na⁺ Optimization (Continued)

- Customers with correlation coefficients applied should reach out to their local Werfen representative if any assistance is needed with this transition.
- See Annex A for a list of part numbers in scope of this field notification.
- For additional support, please contact your local Werfen representative.

Mandatory Customer Actions

Werfen requests that you take the following immediate actions:

- **Evaluate** whether adjustment or removal of Na⁺ correlation coefficients is required prior to implementation of the optimized PAKs, if applicable.
- **Inform** all relevant clinical staff and laboratory personnel of this notification.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.
- **Complete and return** the Mandatory Response Tracking Form **within 10 calendar days** of receipt of this IMPORTANT PRODUCT NOTICE to your local representative.

If you have any technical questions or concerns, please contact your local representative.

Werfen is committed to continuously evaluating and enhancing our products to support high-quality patient care. This upcoming optimization to the GEM Premier 5000 and 7000 PAKs is intended to harmonize normal Na⁺ patient results to the published serum reference range, while maintaining the established performance of the GEM Premier 5000 and GEM Premier 7000 systems.

We appreciate your prompt attention to this notification.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Keith Kelly', is written over a horizontal line.

Keith Kelly
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Annex A
List of part numbers in scope

Part Number	Product Description	UDI-DI
00077407508	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (75 Tests)	00195226000764
00077415008	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (150 Tests)	00195226000757
00077430008	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (300 Tests)	00195226000740
00077445008	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (450 Tests)	00195226000733
00077360008	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (600 Tests)	00195226000726
00077407509	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (75 Tests)	00195226000818
00077415009	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (150 Tests)	00195226000801
00077430009	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (300 Tests)	00195226000795
00077445009	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (450 Tests)	00195226000788
00077360009	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (600 Tests)	00195226000771
00077407510	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (75 Tests)	00195226000665
00077415010	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (150 Tests)	00195226000658
00077430010	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (300 Tests)	00195226000641
00077445010	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (450 Tests)	00195226000634
00077360010	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (600 Tests)	00195226000627
00077407511	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (75 Tests)	00195226000719
00077415011	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (150 Tests)	00195226000702
00077430011	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (300 Tests)	00195226000696
00077445011	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (450 Tests)	00195226000689
00077360011	GEM Premier 7000 with iQM3 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glucose, Lactate, Hct, tHb, tBili, O ₂ Hb, COHb, HHb, MetHb, sO ₂ (600 Tests)	00195226000672

Annex A Cont.'
List of part numbers in scope

Part Number	Product Name	UDI-DI
00055407508	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 75 Test	08426950807612
00055415008	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 150 Test	08426950807674
00055430008	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 300 Test 31 DAYS	08426950807735
00055445008	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 450 Test 31 DAYS	08426950807797
00055360008	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 600 Test 21 DAYS	08426950807575
00055407509	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 75 Test 31 DAYS	08426950807629
00055415009	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 150 Test 31 DAYS	08426950807681
00055430009	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 300 Test 31 DAYS	08426950807742
00055445009	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 450 Test 31 DAYS	08426950807803
00055360009	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 600 Test 21 DAYS	08426950807582
00055407510	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 75 Test 31 DAYS	08426950807636
00055415010	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 150 Test 31 DAYS	08426950807698
00055430010	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 300 Test 31 DAYS	08426950807759
00055445010	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 450 Test	08426950807810
00055360010	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 600 Test	08426950807599
00055407511	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 75 Test	08426950807643
00055415011	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 150 Test	08426950807704
00055430011	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 300 Test	08426950807766
00055445011	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tBili, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 450 Test	08426950807827
00055360010	GEM Premier 5000 PAK pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate, Hct, tHb, O ₂ Hb, COHb, MetHb, HHb, sO ₂ - 600 Test 21 DAYS	08426950807599