



**URGENT FIELD SAFETY NOTICE**  
**GEM PAKs for GEM Premier 5000 with IQM2\***  
**(See List in Appendix A)**

January 20, 2026

Dear Valued GEM Premier 5000 with IQM2 Customer:

This notification is to inform you of a performance issue with the following specific GEM PAKs for the GEM Premier 5000 with IQM2 (Intelligent Quality Management):

Product Name	Part No.	UDI	Lot No.	Expiration Date
GEM PAKs for the GEM Premier 5000 with IQM2	See Appendix A			

**Issue Description and Result Impact**

We have confirmed customer complaints indicating that GEM PAKs (cartridges) for the GEM Premier 5000 listed in **Appendix A** may experience an increased incidence of "Process Control Solution Not Detected" (PCSND) errors during warm-up, including consecutive occurrences, resulting in GEM PAK ejection and requiring insertion of a new GEM PAK. IQM2 is an active quality process control program designed to provide continuous monitoring of the entire testing process. Thus, if a GEM PAK completes AutoPAK Validation following warm-up, it may remain in use.

Consecutive GEM PAK ejections during warm-up may prolong turnaround times, potentially delaying appropriate patient management. In such cases, patient management may require reassessment once results are available. While many GEM PAKs continue to perform as intended, consecutive ejections may increase the likelihood of operational disruption, highlighting the importance of advance planning where feasible to help minimize impact.

To support continuity of patient testing, customers may continue to receive GEM Premier 5000 PAKs listed in Appendix A for a limited period of time.



### **Mandatory Customer Actions**

Please take the following actions immediately:

- **Continue** to use the GEM PAKs for GEM Premier 5000 listed in Appendix A.
- Where feasible, **plan** GEM PAK warm-up cycles with sufficient time to accommodate potential GEM PAK ejections during warm-up.
- Contact your local representative for a replacement, if a GEM PAK experiences a "Process Control Solution Not Detected" error during warm-up.
- **Inform all laboratory staff** of this notification.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

Werfen sincerely apologizes for any inconvenience this situation may cause and is taking immediate action through its established internal quality processes to resolve the issue and restore reliable GEM PAK performance as quickly as possible. Protecting patient safety and minimizing disruption to your patient testing remain our highest priorities.

We appreciate your prompt attention to this Urgent Field Safety Notice and will provide updates as additional information becomes available.

Keith Kelly  
Senior Regulatory Affairs Manager  
Instrumentation Laboratory Co.  
A Werfen Company