



IMPORTANT PRODUCT NOTICE
GEM® PAKs for GEM Premier 5000 with iQM2®

October 17th, 2023

Dear Valued GEM Premier 5000 with iQM2 PAK Customer:

This notification is intended to advise you regarding a potential 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	Please see Appendix: GEM Premier 5000 PAK with iQM2 for a List of Specific Part Numbers, UDI, Lot Numbers and Expiration Dates			

• Issue Description and Impact

Internal testing identified that the GEM PAKs (cartridges) for the GEM Premier 5000 with iQM2 listed in the attached "Appendix: GEM Premier 5000 PAK with iQM2" may experience an increase in APV (Auto PAK Validation) pO_2 failures. If the PAK completes warm-up for pO_2 , the GEM PAK may remain in use.

iQM2 is an active quality process control program designed to provide continuous monitoring of the entire testing process and requires the use of APV (Auto PAK Validation) out of cartridge warm-up prior to running patient samples. When iQM2 disables or flags a parameter, the program is ensuring there is no potential for patient harm.



• Mandatory Customer Actions

Please take the following **immediate** actions:

- **Continue** to use GEM PAKs (cartridges) that pass APV out of warm-up for pO_2 .
- **Contact** your local representative for a replacement GEM PAK, if needed.
- **Share** this information with your laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

We appreciate your prompt attention to this important notification.

Sincerely,

A handwritten signature in blue ink that reads "Anuja Khan".

Anuja Khan
Regulatory Affairs Manager II
Instrumentation Laboratory Co.
A Werfen Company



Appendix: GEM Premier 5000 PAK with iQM2®

Part Number	UDI	Lot No.	Expiration Date
00055360004	00055360004	230912E	2/21/2024
		230824M	2/13/2024
		230914D	2/26/2024
		230907L	2/22/2024
		230913G	2/22/2024
		230927O	3/20/2024
00055360008	08426950807575	230825E	2/19/2024
		230906N	2/16/2024
		230907K	2/22/2024
		230914D	2/26/2024
		230828F	2/16/2024
		230831E	2/16/2024
		230829I	2/15/2024
		230830F	2/16/2024
		230911G	3/1/2024
		230908O	2/22/2024
		230912D	1/23/2024
		230915O	3/1/2024
00055360010	08426950807599	230823H	2/12/2024
		230907G	2/27/2024
		230823Q	2/12/2024
		230825R	2/14/2024
		230825S	2/14/2024
		230828D	2/15/2024
		230828E	2/15/2024
		230906H	2/23/2024
		230908B	2/28/2024
		230908K	2/28/2024
		230913E	2/29/2024
		230919S	1/14/2024
		230830D	2/19/2024
		230907E	2/16/2024
		230905D	2/22/2024
		230829C	2/16/2024
		230906D	2/24/2024
		230828A	2/14/2024
		230828C	2/15/2024
		230912G	2/29/2024
		230824A	1/24/2024
		230911H	2/29/2024
		230822D	1/24/2024
		230825A	2/14/2024
		230822H	1/23/2024
		230822A	1/14/2024
		230824X	2/14/2024
230913C	1/8/2024		
230831A	2/19/2024		

Part Number	UDI	Lot No.	Expiration Date
00055360010	08426950807599	230907C	2/26/2024
		230907H	2/27/2024
		230907M	2/27/2024
		230907J	2/27/2024
		230822B	1/24/2024
		230822G	1/24/2024
		230822M	1/25/2024
		230822N	1/25/2024
		230822O	1/25/2024
		230823J	2/12/2024
		230823K	2/12/2024
		230824R	2/13/2024
		230824S	2/13/2024
		230825P	2/14/2024
		230829N	2/19/2024
		230901O	2/22/2024
		230911L	2/29/2024
		230912A	2/27/2024
		230913K	3/2/2024
		230913N	3/2/2024
		230913P	3/4/2024
		230914C	3/1/2024
		230915B	3/5/2024
		230915D	3/2/2024
		230915K	3/5/2024
		230920H	3/8/2024
		230921F	3/9/2024
		230921I	3/11/2024
		230922A	3/11/2024
		230926F	3/11/2024
		230927B	2/26/2024
		230823N	2/12/2024
		230830A	2/15/2024
230901C	2/21/2024		
231002F	3/30/2024		
231002B	3/30/2024		
00055360011	08426950807605	230831F	2/20/2024
		230831H	2/20/2024
		230825S	2/14/2024
		230823Q	2/12/2024
		230823I	2/12/2024
		230825R	2/14/2024
		230918B	3/4/2024
		230918C	3/4/2024
		230912C	2/29/2024
		230822G	1/24/2024
		230823A	1/25/2024
230823G	2/12/2024		

Part Number	UDI	Lot No.	Expiration Date
00055360011	08426950807605	230823K	2/12/2024
		230824Q	2/13/2024
		230824R	2/13/2024
		230825O	2/13/2024
		230901O	2/22/2024
		230906K	2/26/2024
00055407504	08426950807537	230825E	2/19/2024
		230908O	2/22/2024
		230905G	2/19/2024
		230831E	2/16/2024
		230915O	3/1/2024
		230914D	2/26/2024
		230825F	2/19/2024
		230919P	3/1/2024
		230906N	2/16/2024
		230907L	2/22/2024
		230911F	3/1/2024
		230823C	1/15/2024
		230828G	2/15/2024
		230830F	2/16/2024
		230913G	2/22/2024
		230824M	2/13/2024
		230829H	2/24/2024
		230912E	2/21/2024
		230914J	3/8/2024
		230920F	2/28/2024
		230921T	2/28/2024
		230921U	3/4/2024
		230926J	3/5/2024
		230928F	3/6/2024
00055407508	08426950807612	230906N	2/16/2024
		230905G	2/19/2024
		230823C	1/15/2024
		230825E	2/19/2024
		230828F	2/16/2024
		230830F	2/16/2024
		230908O	2/22/2024
		230915O	3/1/2024
		230822F	1/24/2024
		230907K	2/22/2024
		230829I	2/15/2024
		230912D	1/23/2024
		230911G	3/1/2024
		230914D	2/26/2024
		230918D	2/26/2024
		230920E	2/22/2024
230921T	2/28/2024		
230921U	3/4/2024		

Part Number	UDI	Lot No.	Expiration Date
00055407508	08426950807612	230928E	3/1/2024
00055407510	08426950807636	230907G	2/27/2024
		230907F	2/27/2024
		230915D	3/2/2024
		230829B	2/16/2024
		230912G	2/29/2024
		230914C	3/1/2024
		230905D	2/22/2024
		230822A	1/14/2024
		230828H	2/15/2024
		230831D	2/20/2024
		230908B	2/28/2024
		230919S	1/14/2024
		230913D	2/29/2024
		230830D	2/19/2024
		230825A	2/14/2024
		230907E	2/16/2024
		230824A	1/24/2024
		230828E	2/15/2024
		230824W	2/14/2024
		230906D	2/24/2024
		230912B	2/29/2024
		230829C	2/16/2024
		230831I	2/20/2024
		230913C	1/8/2024
		230911H	2/29/2024
		230831K	2/21/2024
		230831M	2/21/2024
		230831F	2/20/2024
		230831B	2/20/2024
		230830O	2/19/2024
		230831L	2/21/2024
		230828U	2/16/2024
		230829P	2/19/2024
		230822D	1/24/2024
		230822G	1/24/2024
		230822O	1/25/2024
		230823G	2/12/2024
		230823J	2/12/2024
		230823K	2/12/2024
		230824S	2/13/2024
		230911L	2/29/2024
230915A	3/5/2024		
230915K	3/5/2024		
230918O	3/6/2024		
230920H	3/8/2024		
230920K	3/8/2024		
230921F	3/9/2024		

Part Number	UDI	Lot No.	Expiration Date
00055407510	00055407510	230921P	3/11/2024
		230921Q	3/11/2024
		230922A	3/11/2024
		230926F	3/11/2024
00055407511	08426950807643	230907G	2/27/2024
		230825S	2/14/2024
		230829C	2/16/2024
		230824P	2/13/2024
		230828M	2/15/2024
		230831D	2/20/2024
		230912A	2/27/2024
		230824C	2/13/2024
		230906M	2/26/2024
		230822H	1/23/2024
		230906L	2/26/2024
		230823L	2/12/2024
		230906K	2/26/2024
		230822D	1/24/2024
		230822G	1/24/2024
		230822M	1/25/2024
		230822N	1/25/2024
		230822O	1/25/2024
		230824Q	2/13/2024
		230824R	2/13/2024
230927A	3/12/2024		
00055415004	08426950807650	230825E	2/19/2024
		230831E	2/16/2024
		230912E	2/21/2024
		230824M	2/13/2024
		230822F	1/24/2024
		230825F	2/19/2024
		230908O	2/22/2024
		230913G	2/22/2024
		230905G	2/19/2024
		230907L	2/22/2024
		230828G	2/15/2024
		230822E	1/13/2024
		230830F	2/16/2024
		230823C	1/15/2024
		230823Q	2/12/2024
		230914D	2/26/2024
		230914J	3/8/2024
		230915O	3/1/2024
		230919P	3/1/2024
		230920F	2/28/2024
230921T	2/28/2024		
230926J	3/5/2024		
00055415004	08426950807650	230928F	3/6/2024

Part Number	UDI	Lot No.	Expiration Date
00055415005	08426950807667	230831E	2/16/2024
00055415008	08426950807674	230831E	2/16/2024
		230828F	2/16/2024
		230830F	2/16/2024
		230825E	2/19/2024
		230905F	2/22/2024
		230913F	2/24/2024
		230822F	1/24/2024
		230908B	2/28/2024
		230901E	2/16/2024
		230823O	2/12/2024
		230912D	1/23/2024
		230907K	2/22/2024
		230823C	1/15/2024
		230901P	2/22/2024
		230905P	2/23/2024
		230908O	2/22/2024
		230914D	2/26/2024
		230915O	3/1/2024
		230918D	2/26/2024
		230920E	2/22/2024
230921U	3/4/2024		
00055415009	08426950807681	230825E	2/19/2024
00055415010	08426950807698	230823H	2/12/2024
		230829K	2/16/2024
		230831F	2/20/2024
		230825R	2/14/2024
		230907G	2/27/2024
		230830D	2/19/2024
		230907E	2/16/2024
		230913D	2/29/2024
		230906C	2/23/2024
		230824W	2/14/2024
		230830J	2/19/2024
		230831D	2/20/2024
		230905C	2/21/2024
		230824A	1/24/2024
		230822A	1/14/2024
		230822K	1/21/2024
		230829C	2/16/2024
		230912L	1/24/2024
		230908B	2/28/2024
		230824V	2/14/2024
		230828H	2/15/2024
		230828I	2/15/2024
		230912B	2/29/2024
230906D	2/24/2024		
230915C	3/5/2024		

Part Number	UDI	Lot No.	Expiration Date
00055415010	08426950807698	230907B	2/26/2024
		230907C	2/26/2024
		230824D	2/13/2024
		230828B	2/15/2024
		230824S	2/13/2024
		230831B	2/20/2024
		230823M	2/12/2024
		230823N	2/12/2024
		230824T	2/13/2024
		230828A	2/14/2024
		230822D	1/24/2024
		230822G	1/24/2024
		230822H	1/23/2024
		230822O	1/25/2024
		230823G	2/12/2024
		230823J	2/12/2024
		230823K	2/12/2024
		230824R	2/13/2024
		230829N	2/19/2024
		230829O	2/19/2024
		230830M	2/19/2024
		230830N	2/19/2024
		230830Q	2/19/2024
		230831M	2/21/2024
		230905A	2/21/2024
		230911L	2/29/2024
		230914A	3/4/2024
		230914C	3/1/2024
		230915J	3/5/2024
		230918A	3/5/2024
		230918L	3/6/2024
		230918M	3/6/2024
		230919E	3/7/2024
230919F	3/7/2024		
230919O	3/6/2024		
230920I	3/8/2024		
230921F	3/9/2024		
230926Q	3/20/2024		
230927J	3/12/2024		
00055415011	08426950807704	230831F	2/20/2024
		230823I	2/12/2024
		230825S	2/14/2024
		230825C	2/14/2024
		230914A	3/4/2024
		230919L	3/7/2024
		230919U	3/4/2024
		230915C	3/5/2024
230906B	2/23/2024		

Part Number	UDI	Lot No.	Expiration Date
00055415011	08426950807704	230824T	2/13/2024
		230825A	2/14/2024
		230831D	2/20/2024
		230824X	2/14/2024
		230828Q	2/16/2024
		230907A	2/26/2024
		230822L	1/24/2024
		230822D	1/24/2024
		230822G	1/24/2024
		230823G	2/12/2024
		230823J	2/12/2024
		230823K	2/12/2024
		230824Q	2/13/2024
		230824R	2/13/2024
		230824S	2/13/2024
		230825P	2/14/2024
		230831A	2/19/2024
		230918F	3/4/2024
		230919V	3/7/2024
		230920L	3/8/2024
230921O	3/4/2024		
230926M	3/11/2024		
00055430004	08426950807711	230825E	2/19/2024
		230907L	2/22/2024
		230908O	2/22/2024
		230905G	2/19/2024
		230822E	1/13/2024
		230906N	2/16/2024
		230913F	2/24/2024
		230912E	2/21/2024
		230831E	2/16/2024
		230823C	1/15/2024
		230918D	2/26/2024
		230824M	2/13/2024
		230911F	3/1/2024
		230824E	2/12/2024
		230828G	2/15/2024
		230824U	2/17/2024
		230830F	2/16/2024
		230915O	3/1/2024
		230825F	2/19/2024
		230829H	2/24/2024
230913G	2/22/2024		
230914J	3/8/2024		
230919P	3/1/2024		
230920F	2/28/2024		
230921T	2/28/2024		
230921U	3/4/2024		



Part Number	UDI	Lot No.	Expiration Date
00055430004	08426950807711	230928F	3/6/2024
00055430008	08426950807735	230828F	2/16/2024
		230830F	2/16/2024
		230901E	2/16/2024
		230912D	1/23/2024
		230822F	1/24/2024
		230906J	2/24/2024
		230825E	2/19/2024
		230906K	2/26/2024
		230907K	2/22/2024
		230913F	2/24/2024
		230919J	3/1/2024
		230920E	2/22/2024
		230921T	2/28/2024
		230928E	3/1/2024
00055430010	08426950807759	230823H	2/12/2024
		230823I	2/12/2024
		230825R	2/14/2024
		230829K	2/16/2024
		230823Q	2/12/2024
		230823R	2/13/2024
		230907G	2/27/2024
		230907B	2/26/2024
		230912L	1/24/2024
		230908B	2/28/2024
		230911H	2/29/2024
		230830J	2/19/2024
		230905B	1/14/2024
		230824N	2/13/2024
		230824R	2/13/2024
		230825H	2/14/2024
		230913D	2/29/2024
		230824A	1/24/2024
		230831D	2/20/2024
		230822A	1/14/2024
		230905N	2/23/2024
		230828Q	2/16/2024
		230828U	2/16/2024
		230828V	2/16/2024
		230828T	2/15/2024
		230906B	2/23/2024
		230828I	2/15/2024
		230905C	2/21/2024
		230905D	2/22/2024
		230905J	2/22/2024
230905Q	2/23/2024		
230824V	2/14/2024		
230914C	3/1/2024		

Part Number	UDI	Lot No.	Expiration Date
00055430010	08426950807759	230912C	2/29/2024
		230829A	2/16/2024
		230906A	2/23/2024
		230824T	2/13/2024
		230829D	2/15/2024
		230828J	2/15/2024
		230824D	2/13/2024
		230823L	2/12/2024
		230822G	1/24/2024
		230822H	1/23/2024
		230822N	1/25/2024
		230822O	1/25/2024
		230823G	2/12/2024
		230823J	2/12/2024
		230823K	2/12/2024
		230824S	2/13/2024
		230824X	2/14/2024
		230828B	2/15/2024
		230829N	2/19/2024
		230829O	2/19/2024
		230911L	2/29/2024
		230912S	3/1/2024
		230914A	3/4/2024
		230914B	3/4/2024
		230915D	3/2/2024
		230915E	3/2/2024
		230915H	3/2/2024
		230918F	3/4/2024
		230919D	3/6/2024
		230919H	3/7/2024
		230920K	3/8/2024
		230921I	3/11/2024
		230926F	3/11/2024
230926H	3/11/2024		
230901C	2/21/2024		
230822L	1/24/2024		
230830A	2/15/2024		
231002F	3/30/2024		
00055430011	08426950807766	230823H	2/12/2024
		230823Q	2/12/2024
		230907G	2/27/2024
		230913B	3/1/2024
		230914A	3/4/2024
		230913Q	3/4/2024
		230912C	2/29/2024
		230824Q	2/13/2024
		230905A	2/21/2024
		230831D	2/20/2024

Part Number	UDI	Lot No.	Expiration Date
00055430011	08426950807766	230824X	2/14/2024
		230906B	2/23/2024
		230828A	2/14/2024
		230912A	2/27/2024
		230911E	2/21/2024
		230822L	1/24/2024
		230822M	1/25/2024
		230907B	2/26/2024
		230822G	1/24/2024
		230822N	1/25/2024
		230823J	2/12/2024
		230823K	2/12/2024
		230824R	2/13/2024
		230829N	2/19/2024
		230920Q	3/8/2024
		230921E	3/9/2024
		230921O	3/4/2024
00055445004	08426950807773	230829H	2/24/2024
		230914D	2/26/2024
		230905G	2/19/2024
		230913G	2/22/2024
		230919P	3/1/2024
		230823C	1/15/2024
		230822E	1/13/2024
		230831E	2/16/2024
		230830F	2/16/2024
		230906N	2/16/2024
		230828G	2/15/2024
		230907L	2/22/2024
		230908O	2/22/2024
		230912E	2/21/2024
		230915O	3/1/2024
		230920F	2/28/2024
		230921T	2/28/2024
230921U	3/4/2024		
00055445008	08426950807797	230830F	2/16/2024
		230831E	2/16/2024
		230907K	2/22/2024
		230913F	2/24/2024
		230823C	1/15/2024
		230823O	2/12/2024
		230829I	2/15/2024
		230825E	2/19/2024
		230828F	2/16/2024
		230918D	2/26/2024
		230919J	3/1/2024
		230920E	2/22/2024
230928E	3/1/2024		



Part Number	UDI	Lot No.	Expiration Date
00055445008	08426950807797	230824E	2/12/2024
00055445010	08426950807810	230823H	2/12/2024
		230825Q	2/14/2024
		230825T	2/14/2024
		230907G	2/27/2024
		230823R	2/13/2024
		230823I	2/12/2024
		230823G	2/12/2024
		230907F	2/27/2024
		230824S	2/13/2024
		230905B	1/14/2024
		230830C	2/13/2024
		230913E	2/29/2024
		230828J	2/15/2024
		230831D	2/20/2024
		230824V	2/14/2024
		230901I	2/21/2024
		230829A	2/16/2024
		230830J	2/19/2024
		230907I	2/27/2024
		230824A	1/24/2024
		230905A	2/21/2024
		230822L	1/24/2024
		230906B	2/23/2024
		230828B	2/15/2024
		230828C	2/15/2024
		230912C	2/29/2024
		230822K	1/21/2024
		230828K	2/15/2024
		230911C	1/14/2024
		230908A	2/27/2024
		230907A	2/26/2024
		230907B	2/26/2024
		230823L	2/12/2024
		230824T	2/13/2024
		230824X	2/14/2024
		230911B	2/28/2024
		230911D	2/29/2024
		230908B	2/28/2024
		230825A	2/14/2024
		230908C	2/28/2024
		230906A	2/23/2024
		230901A	2/21/2024
230901B	2/21/2024		
230822B	1/24/2024		
230822D	1/24/2024		
230822G	1/24/2024		
230822H	1/23/2024		

Part Number	UDI	Lot No.	Expiration Date
00055445010	08426950807810	230822M	1/25/2024
		230822N	1/25/2024
		230822O	1/25/2024
		230823J	2/12/2024
		230823K	2/12/2024
		230824Q	2/13/2024
		230824R	2/13/2024
		230829N	2/19/2024
		230829O	2/19/2024
		230906C	2/23/2024
		230911L	2/29/2024
		230914C	3/1/2024
		230915C	3/5/2024
		230915D	3/2/2024
		230915E	3/2/2024
		230915H	3/2/2024
		230918Q	3/7/2024
		230919B	3/7/2024
		230919E	3/7/2024
		230919I	3/7/2024
		230920D	3/8/2024
		230920H	3/8/2024
		230920L	3/8/2024
		230920Q	3/8/2024
		230920R	3/8/2024
		230921D	3/7/2024
		230921F	3/9/2024
		230926H	3/11/2024
		230926I	3/11/2024
		230927D	3/1/2024
		230823P	2/12/2024
		230829P	2/19/2024
		230829Q	2/19/2024
230830A	2/15/2024		
230830B	2/19/2024		
00055445011	08426950807827	230823G	2/12/2024
		230823H	2/12/2024
		230823I	2/12/2024
		230831F	2/20/2024
		230907G	2/27/2024
		230823L	2/12/2024
		230823M	2/12/2024
		230824X	2/14/2024
		230829D	2/15/2024
		230831I	2/20/2024
		230912C	2/29/2024
		230823R	2/13/2024
230824B	2/13/2024		

Part Number	UDI	Lot No.	Expiration Date
00055445011	08426950807827	230911H	2/29/2024
		230912A	2/27/2024
		230912R	3/1/2024
		230906B	2/23/2024
		230907F	2/27/2024
		230907I	2/27/2024
		230912S	3/1/2024
		230822M	1/25/2024
		230822O	1/25/2024
		230906K	2/26/2024
		230822G	1/24/2024
		230823K	2/12/2024
		230824R	2/13/2024
		230824S	2/13/2024
		230825P	2/14/2024
		230831B	2/20/2024
		230901O	2/22/2024
		230921F	3/9/2024
		230926I	3/11/2024
		230830B	2/19/2024