



To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 29 dated 3/3/24 Regarding NCMDR FSQA of GEM® PAKs for GEM Premier 3000 with iQM® and GEM Premier 3500 with iQM®, GEM Premier 4000 with iQM®, GEM Premier 5000 with iQM2® from (mfr: from Instrumentation Laboratory Co).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 29 / 2024

22-08-1445 H
03-03-2024

تحت إشراف
مديريتنا
نسير قدماً
معاً
2024



FSCA of GEM® PAKs for GEM Premier 3000 with iQM® and GEM Premier 3500 with iQM®, GEM Premier 4000 with iQM®, GEM Premier 5000 with iQM2® from Instrumentation Laboratory Co.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19936
Product	GEM® PAKs for GEM Premier 3000 with iQM® and GEM Premier 3500 with iQM®, GEM Premier 4000 with iQM®, GEM Premier 5000 with iQM2®.
Description	IVD.
Manufacturer	Instrumentation Laboratory Co.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Kindly refer to the attachment.
Reason	GEM PAKs (cartridges) for GEM Premier listed in the attachment may experience an increase in GEM CVP Level 1 pO2 failures.
Action	<ol style="list-style-type: none">1. Ensure the iQM is enabled for all the listed PAKs and GEM CVPs are run according to Instructions for Use.2. Continue to use the GEM PAKs (cartridges) that passes GEM CVP out of warm-up for pO2.3. Contact your local Werfen distributor for a replacement GEM PAK, if GEM CVP does not pass pO2.4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

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Dr. Mohammed Handan Al Rubaie
Director General

ص ب ٣٩٣ مسقط - الرقم القيدى ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٤٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om



IMPORTANT PRODUCT NOTICE **GEM® PAKs for GEM Premier 3000 with iQM® and** **GEM Premier 3500 with iQM®**

October 17th, 2023

Dear Valued GEM Premier 3000/3500 with iQM Customer:

This notification is intended to advise you regarding a potential performance issue with the following specific GEM PAKs for the GEM Premier 3000/3500 with iQM (Intelligent Quality Management):

Product Name	Part No.	UDI	Lot No.	Expiration Date
GEM PAKs for the GEM Premier 3000/3500 with iQM	Please see Appendix: GEM Premier 3X00 PAK with iQM 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 3000/3500 with iQM listed in the attached "Appendix: GEM Premier 3X00 PAK with iQM" may experience an increase in GEM CVP Level 1 pO_2 failures. If the GEM PAK completes warm-up and passes GEM CVP for pO_2 , the GEM PAK may remain in use.

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

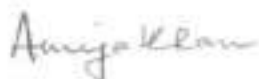
• **Mandatory Customer Actions**

Please take the following **immediate** actions:

- **Ensure** the IQM is enabled for all the listed PAKs and GEM CVPs are run according to Instructions for Use.
- **Continue** to use the GEM PAKs (cartridges) that passes GEM CVP out of warm-up for pO_2 .
- **Contact** your local Werfen representative for a replacement GEM PAK, if GEM CVP does not pass pO_2 .
- **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,



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



Appendix: GEM Premier 3X00 PAK with IQM®

Part No.	UDI	Lot No.	Expiration Date
00024307584	08426950087960	323033I	2/14/2024
		323733H	2/21/2024
		325233B	3/7/2024
00024307587	08426950087984	323434D	2/18/2024
		324234I	2/26/2024
		325234B	3/7/2024
		325634F	3/11/2024
00024307589	08426950088004	323139A	2/15/2024
		323139B	2/15/2024
		323139D	2/15/2024
		323339K	2/17/2024
		323439F	2/18/2024
		323439H	2/18/2024
		323739D	2/21/2024
		323739G	2/21/2024
		323739J	2/21/2024
		324139D	2/25/2024
		324139G	2/25/2024
		324239C	2/26/2024
		324339G	2/27/2024
		324539A	2/29/2024
		324939E	3/4/2024
		325639B	3/11/2024
325639D	3/11/2024		
00024315084	08426950082361	323043I	2/14/2024
		323843E	2/22/2024
		324143H	2/25/2024
		324343H	2/27/2024

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Part No.	UDI	Lot No.	Expiration Date
00024315084	08426950082361	325643F	3/11/2024
00024315087	08426950082378	323744H	2/21/2024
		323844E	2/22/2024
		324044H	2/24/2024
		324144H	2/25/2024
		324244G	2/26/2024
		324344H	2/27/2024
		325244B	3/7/2024
		325644F	3/11/2024
00024315089	08426950082385	326344E	3/18/2024
		323046K	2/14/2024
		323146A	2/15/2024
		323146D	2/15/2024
		323346K	2/17/2024
		323446F	2/18/2024
		323546F	2/19/2024
		323546I	2/19/2024
		323746C	2/21/2024
		323746D	2/21/2024
		323746J	2/21/2024
		323846A	2/22/2024
		324146I	2/25/2024
		324346G	2/27/2024
325146A	3/6/2024		
325746A	3/12/2024		
00024330084	08426950082392	324257G	2/26/2024
		323057I	2/14/2024
00024330087	08426950082408	323054I	2/14/2024
		323854E	2/22/2024
		324354H	2/27/2024

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Part No.	UDI	Lot No.	Expiration Date
00024330087	08426950082408	324854E	3/3/2024
		324854G	3/3/2024
		325754H	3/12/2024
		325954A	3/14/2024
		326354E	3/18/2024
00024330089	08426950082415	323156B	2/15/2024
		323156C	2/15/2024
		323356G	2/17/2024
		323356K	2/17/2024
		323456F	2/18/2024
		323556F	2/19/2024
		323656I	2/20/2024
		323756D	2/21/2024
		323756G	2/21/2024
		324056G	2/24/2024
		324056P	2/24/2024
		324156G	2/25/2024
		324256B	2/26/2024
		324956E	3/4/2024
		325756A	3/12/2024
00024345087	08426950082439	323064I	2/14/2024
00024345089	08426950082446	323066J	2/14/2024
		323366K	2/17/2024
		323466C	2/18/2024
		323466F	2/18/2024
		323666C	2/20/2024
		323766D	2/21/2024
		324166I	2/25/2024
		324266J	2/26/2024
		324966B	3/4/2024
		324966E	3/4/2024

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Part No.	UDI	Lot No.	Expiration Date
00024403584	08426950452430	323023I	2/14/2024
		324223I	2/26/2024
		324823G	3/3/2024
		325223B	3/7/2024
00024407584	08426950088189	323835E	2/22/2024
		324935F	3/4/2024
00024407587	08426950452447	323037I	2/14/2024
		323737H	2/21/2024
		323837E	2/22/2024
		324037H	2/24/2024
		324237G	2/26/2024
		324337H	2/27/2024
		325237B	3/7/2024
00026307587	08426950511571	323034I	2/14/2024
		323834E	2/22/2024
		324034H	2/24/2024
		324234I	2/26/2024
		325234B	3/7/2024
		325634F	3/11/2024
		325934A	3/14/2024
00026307589	08426950511588	323039A	2/14/2024
		323039D	2/14/2024
		323039J	2/14/2024
		323139A	2/15/2024
		323139B	2/15/2024
		323139C	2/15/2024
		323139D	2/15/2024
		323339G	2/17/2024
		323339I	2/17/2024
		323339J	2/17/2024
		323339K	2/17/2024
		323439A	2/18/2024

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Part No.	UDI	Lot No.	Expiration Date
00026307589	08426950511588	323439C	2/18/2024
		323439E	2/18/2024
		323439F	2/18/2024
		323439H	2/18/2024
		323539C	2/19/2024
		323539E	2/19/2024
		323539F	2/19/2024
		323539I	2/19/2024
		323539J	2/19/2024
		323639A	2/20/2024
		323639B	2/20/2024
		323639C	2/20/2024
		323639I	2/20/2024
		323739A	2/21/2024
		323739B	2/21/2024
		323739C	2/21/2024
		323739D	2/21/2024
		323739G	2/21/2024
		323739I	2/21/2024
		323739J	2/21/2024
		323839D	2/22/2024
		324039F	2/24/2024
		324039O	2/24/2024
		324139A	2/25/2024
		324139B	2/25/2024
		324139D	2/25/2024
		324139E	2/25/2024
		324139G	2/25/2024
324139I	2/25/2024		
324139K	2/25/2024		
324239B	2/26/2024		
324239H	2/26/2024		

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Part No.	UDI	Lot No.	Expiration Date
00026307589	08426950511588	324239J	2/26/2024
		324339B	2/27/2024
		324339C	2/27/2024
		324339E	2/27/2024
		324339F	2/27/2024
		324339G	2/27/2024
		324539A	2/29/2024
		324839B	3/3/2024
		324839F	3/3/2024
		324939B	3/4/2024
		324939E	3/4/2024
		325039A	3/5/2024
		325039E	3/5/2024
		325439F	3/9/2024
		325439H	3/9/2024
		325539A	3/10/2024
		325539J	3/10/2024
		325639B	3/11/2024
		325739C	3/12/2024
		326139G	3/16/2024
326139H	3/16/2024		
326439E	3/19/2024		
00026315084	08426950511595	323043F	2/14/2024
		323043H	2/14/2024
		323043I	2/14/2024
		323443D	2/18/2024
		323643E	2/20/2024
		323643G	2/20/2024
		323743H	2/21/2024
		323843E	2/22/2024
		324043H	2/24/2024
		324243G	2/26/2024

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Part No.	UDI	Lot No.	Expiration Date
00026315084	08426950511595	324343H	2/27/2024
		324843G	3/3/2024
		324943F	3/4/2024
		325043H	3/5/2024
		325243B	3/7/2024
		325643F	3/11/2024
		325743G	3/12/2024
00026315087	08426950511601	323044I	2/14/2024
		323544D	2/19/2024
		323644G	2/20/2024
		323744H	2/21/2024
		323844E	2/22/2024
		324044H	2/24/2024
		324144H	2/25/2024
		324144J	2/25/2024
		324244G	2/26/2024
		324244I	2/26/2024
		324344H	2/27/2024
		324344I	2/27/2024
		324844G	3/3/2024
		324944F	3/4/2024
		325044C	3/5/2024
		325044D	3/5/2024
		325044H	3/5/2024
		325244B	3/7/2024
		325644F	3/11/2024
		325744H	3/12/2024
325844G	3/13/2024		
325944A	3/14/2024		
00026315089	08426950511618	323046D	2/14/2024

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Part No.	UDI	Lot No.	Expiration Date
00026315089	08426950511618	323046E	2/14/2024
		323046J	2/14/2024
		323046K	2/14/2024
		323146A	2/15/2024
		323146B	2/15/2024
		323146C	2/15/2024
		323146D	2/15/2024
		323346E	2/17/2024
		323346F	2/17/2024
		323346I	2/17/2024
		323346J	2/17/2024
		323346K	2/17/2024
		323346L	2/17/2024
		323446A	2/18/2024
		323446E	2/18/2024
		323446F	2/18/2024
		323446G	2/18/2024
		323446H	2/18/2024
		323546B	2/19/2024
		323546C	2/19/2024
		323546F	2/19/2024
		323546I	2/19/2024
		323646D	2/20/2024
		323646H	2/20/2024
		323646I	2/20/2024
		323646J	2/20/2024
		323746A	2/21/2024
		323746D	2/21/2024
		323746G	2/21/2024
		323746J	2/21/2024
323846A	2/22/2024		
324046F	2/24/2024		

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Part No.	UDI	Lot No.	Expiration Date
00026315089	08426950511618	324046G	2/24/2024
		324046I	2/24/2024
		324046J	2/24/2024
		324046N	2/24/2024
		324046P	2/24/2024
		324146D	2/25/2024
		324146E	2/25/2024
		324146F	2/25/2024
		324146G	2/25/2024
		324146I	2/25/2024
		324246A	2/26/2024
		324246B	2/26/2024
		324246F	2/26/2024
		324246J	2/26/2024
		324346A	2/27/2024
		324346B	2/27/2024
		324346C	2/27/2024
		324346D	2/27/2024
		324346G	2/27/2024
		324446C	2/28/2024
		324846B	3/3/2024
		324846C	3/3/2024
		324846F	3/3/2024
		324946E	3/4/2024
		325046A	3/5/2024
		325146B	3/6/2024
		325446F	3/9/2024
		325546G	3/10/2024
		325646B	3/11/2024
		325746C	3/12/2024
326146H	3/16/2024		
326446E	3/19/2024		

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Part No.	UDI	Lot No.	Expiration Date
00026330084	08426950511625	323057I	2/14/2024
		323657E	2/20/2024
		323657G	2/20/2024
		323757H	2/21/2024
		323857E	2/22/2024
		324057H	2/24/2024
		324157H	2/25/2024
		324157J	2/25/2024
		324257G	2/26/2024
		324257I	2/26/2024
		324357H	2/27/2024
		324857G	3/3/2024
		324957F	3/4/2024
		325057B	3/5/2024
		325057D	3/5/2024
		325257B	3/7/2024
		325657F	3/11/2024
		325757G	3/12/2024
00026330087	08426950511632	323054I	2/14/2024
		323654G	2/20/2024
		323754H	2/21/2024
		323854E	2/22/2024
		324154H	2/25/2024
		324254G	2/26/2024
		324254I	2/26/2024
		324354H	2/27/2024
		324854G	3/3/2024
		324954F	3/4/2024
		325054C	3/5/2024
		325054H	3/5/2024
		325254B	3/7/2024
		325654F	3/11/2024

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Part No.	UDI	Lot No.	Expiration Date
00026330087	08426950511632	325954A	3/14/2024
00026330089	08426950511649	323056A	2/14/2024
		323056E	2/14/2024
		323056J	2/14/2024
		323056K	2/14/2024
		323156A	2/15/2024
		323156B	2/15/2024
		323156C	2/15/2024
		323156D	2/15/2024
		323356F	2/17/2024
		323356K	2/17/2024
		323456F	2/18/2024
		323456G	2/18/2024
		323456H	2/18/2024
		323556I	2/19/2024
		323656D	2/20/2024
		323656H	2/20/2024
		323656I	2/20/2024
		323756D	2/21/2024
		323756G	2/21/2024
		323756J	2/21/2024
		323856A	2/22/2024
		324056J	2/24/2024
		324056P	2/24/2024
		324156B	2/25/2024
		324156C	2/25/2024
		324156D	2/25/2024
		324156E	2/25/2024
		324156F	2/25/2024
		324156G	2/25/2024
		324156I	2/25/2024
324156K	2/25/2024		

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Part No.	UDI	Lot No.	Expiration Date
00026330089	08426950511649	324256B	2/26/2024
		324256C	2/26/2024
		324256F	2/26/2024
		324256J	2/26/2024
		324256K	2/26/2024
		324356A	2/27/2024
		324356E	2/27/2024
		324356F	2/27/2024
		324356G	2/27/2024
		324456A	2/28/2024
		324456B	2/28/2024
		324956E	3/4/2024
		325056E	3/5/2024
		325056I	3/5/2024
		325456E	3/9/2024
		325556A	3/10/2024
		325556D	3/10/2024
		325556G	3/10/2024
		325756C	3/12/2024
		325756D	3/12/2024
325856B	3/13/2024		
326156H	3/16/2024		
00026345084	08426950511656	323063F	2/14/2024
		323063H	2/14/2024
		324163H	2/25/2024
		324263G	2/26/2024
		324863G	3/3/2024
		324963F	3/4/2024
		325063C	3/5/2024
		325763G	3/12/2024

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Part No.	UDI	Lot No.	Expiration Date
00026345087	08426950508632	323064I	2/14/2024
		323464B	2/18/2024
		323664G	2/20/2024
		323764H	2/21/2024
		324064H	2/24/2024
		324164J	2/25/2024
		324864G	3/3/2024
		325064C	3/5/2024
		325664F	3/11/2024
00026345089	08426950511663	323066E	2/14/2024
		323066J	2/14/2024
		323066K	2/14/2024
		323166A	2/15/2024
		323166B	2/15/2024
		323166C	2/15/2024
		323166D	2/15/2024
		323366K	2/17/2024
		323466F	2/18/2024
		323466G	2/18/2024
		323466H	2/18/2024
		323566A	2/19/2024
		323566F	2/19/2024
		323566I	2/19/2024
		323666D	2/20/2024
		323666H	2/20/2024
		323666I	2/20/2024
		323766D	2/21/2024
		323766G	2/21/2024
		323766J	2/21/2024
		324066P	2/24/2024
324166C	2/25/2024		
324166D	2/25/2024		

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Part No.	UDI	Lot No.	Expiration Date
00026345089	08426950511663	324166F	2/25/2024
		324166G	2/25/2024
		324166I	2/25/2024
		324266A	2/26/2024
		324266D	2/26/2024
		324266F	2/26/2024
		324266H	2/26/2024
		324266J	2/26/2024
		324266L	2/26/2024
		324266N	2/26/2024
		324366G	2/27/2024
		324466B	2/28/2024
		324866B	3/3/2024
		324866C	3/3/2024
		324966B	3/4/2024
		324966E	3/4/2024
		325466E	3/9/2024
		325666A	3/11/2024
		325666B	3/11/2024
00026360084	08426950511670	323773H	2/21/2024
		324073H	2/24/2024
		324173H	2/25/2024
		324973F	3/4/2024
		325073H	3/5/2024
		325273B	3/7/2024
00026360087	08426950511687	323774H	2/21/2024
		325074C	3/5/2024
		325074H	3/5/2024
00026360089	08426950511694	323076J	2/14/2024
		323076K	2/14/2024
		323176B	2/15/2024
		323176C	2/15/2024

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Part No.	UDI	Lot No.	Expiration Date
00026360089	08426950511694	323176D	2/15/2024
		323376E	2/17/2024
		323376F	2/17/2024
		323376K	2/17/2024
		323476F	2/18/2024
		323576A	2/19/2024
		323576F	2/19/2024
		323576I	2/19/2024
		323676C	2/20/2024
		323676D	2/20/2024
		323776D	2/21/2024
		323776G	2/21/2024
		324076P	2/24/2024
		324176D	2/25/2024
		324176E	2/25/2024
		324176I	2/25/2024
		324276A	2/26/2024
		324276D	2/26/2024
		324376A	2/27/2024
		324376G	2/27/2024
		324476B	2/28/2024
		324976B	3/4/2024
		324976E	3/4/2024
		324976G	3/4/2024
		325476F	3/9/2024
325576G	3/10/2024		
		325576J	3/10/2024

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Part No.	UDI	Lot No.	Expiration Date
00026403584	08426950511533	323023I	2/14/2024
		323723H	2/21/2024
		323823E	2/22/2024
		324023H	2/24/2024
		324123H	2/25/2024
		324223G	2/26/2024
		324223I	2/26/2024
		324323H	2/27/2024
		324923F	3/4/2024
		325223B	3/7/2024
00026407584	08426950511540	323035I	2/14/2024
		323435B	2/18/2024
		323635G	2/20/2024
		323735H	2/21/2024
		323835E	2/22/2024
		324035H	2/24/2024
		324135J	2/25/2024
		324235G	2/26/2024
		324335H	2/27/2024
		324835G	3/3/2024
		324935F	3/4/2024
		325035D	3/5/2024
		325235B	3/7/2024
325635F	3/11/2024		
00026407587	08426950511564	323037I	2/14/2024
		323637G	2/20/2024
		323737H	2/21/2024
		323837E	2/22/2024
		324037H	2/24/2024
		324137H	2/25/2024
		324237G	2/26/2024
		324237I	2/26/2024

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Part No.	UDI	Lot No.	Expiration Date
00026407587	08426950511564	324337H	2/27/2024
		324837G	3/3/2024
		324937F	3/4/2024
		325237B	3/7/2024
		325837G	3/13/2024

IMPORTANT PRODUCT NOTICE GEM® PAKs for GEM Premier 4000 with iQM®

October 17th, 2023

Dear Valued GEM Premier 4000 with iQM Customer:

This notification is intended to advise you regarding a potential performance issue with the following specific GEM PAKs for the GEM Premier 4000 with iQM (Intelligent Quality Management) PAKs:

Product Name	Part No.	UDI	Lot No.	Expiration Date
GEM PAKs for the GEM Premier 4000 with iQM	Please see Appendix: GEM Premier 4000 PAK with iQM 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 4000 with iQM listed in the attached "Appendix: GEM Premier 4000 PAK with iQM" may experience an increase in GEM CVP Level 1 pO_2 failures. If the PAK completes warm-up and passes GEM CVP for pO_2 , the GEM PAK may remain in use.

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

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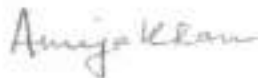
• Mandatory Customer Actions

Please take the following **immediate** actions:

- **Continue** to use the GEM PAKs (cartridges) that passes GEM CVP out of warm-up for pO_2 .
- **Contact** your local Werfen Representative for a replacement GEM PAK, if GEM CVP does not pass pO_2 .
- **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,



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

Appendix: GEM Premier 4000 PAK with IQM®

Part No.	UDI	Lot No.	Expiration Date
00027407504	08426950554806	230825A	2/2/2024
00027445005	08426950554752	230824J	1/28/2024
00027407510	08426950461081	230824G	2/3/2024
		230906H	2/11/2024
		230817K	1/28/2024
		230822G	2/4/2024
		230821K	2/7/2024
		230821I	2/7/2024
		230817H	1/28/2024
		230901D	2/10/2024
		230824J	1/28/2024
		230829B	2/3/2024
		230818E	1/31/2024
		230830N	2/7/2024
		230914C	2/18/2024
		230908F	2/15/2024
		230908G	2/15/2024
		230901H	2/10/2024
		230908E	2/15/2024
		230821L	2/7/2024
		230828M	2/3/2024
		00027415010	08426950440703
230830L	2/7/2024		
230831E	2/8/2024		
230831F	2/8/2024		
230906G	2/11/2024		
230831L	2/9/2024		
230822D	1/28/2024		
230822G	2/4/2024		
230821K	2/7/2024		
230824J	1/28/2024		
230821I	2/7/2024		
230828L	2/14/2024		
230830M	2/7/2024		
230831D	2/9/2024		
230824E	2/8/2024		
230817I	1/28/2024		
230824H	2/3/2024		
230821F	2/1/2024		
230906K	2/11/2024		
230907L	2/14/2024		
230911M	2/16/2024		
230912C	2/16/2024		

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Part No.	UDI	Lot No.	Expiration Date
00027430010	08426950440697	230901B	2/9/2024
		230901C	2/9/2024
		230821K	2/7/2024
		230824J	1/28/2024
		230831G	2/8/2024
		230830E	2/4/2024
		230818I	1/28/2024
		230821I	2/7/2024
		230824H	2/3/2024
		230817I	1/28/2024
		230824E	2/8/2024
		230829G	2/3/2024
		230817H	1/28/2024
		230828L	2/14/2024
		230823I	2/1/2024
		230830M	2/7/2024
		230822H	2/1/2024
		230824B	2/2/2024
		230817C	1/11/2024
		230821B	1/28/2024
230821C	1/28/2024		
230823M	2/1/2024		
00027445010	08426950441304	230831E	2/8/2024
		230830E	2/4/2024
		230822D	1/28/2024
		230830M	2/7/2024
		230906H	2/11/2024
		230821I	2/7/2024
		230821K	2/7/2024
		230824J	1/28/2024
		230817I	1/28/2024
		230818I	1/28/2024
		230818H	2/2/2024
		230901G	2/10/2024
		230828L	2/14/2024
		230822H	2/1/2024
		230908C	2/15/2024
		230828C	2/3/2024
		230825K	2/2/2024
		230828D	2/3/2024
230908D	2/15/2024		

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Part No.	UDI	Lot No.	Expiration Date
00027360010	08426950465379	230830L	2/7/2024
		230822G	2/4/2024
		230906H	2/11/2024
		230817I	1/28/2024
		230830M	2/7/2024
		230821I	2/7/2024
		230821K	2/7/2024
		230822I	2/1/2024
		230818H	2/2/2024
		230828L	2/14/2024
		230825K	2/2/2024
00027407511	08426950554714	230828L	2/14/2024
		230822J	2/1/2024
		230906J	2/11/2024
		230906K	2/11/2024
		230912E	2/15/2024
		230823C	2/1/2024
		230912G	2/17/2024
00027415011	08426950485728	230912D	2/17/2024
		230824G	2/3/2024
		230831K	2/9/2024
		230821I	2/7/2024
		230901B	2/9/2024
		230901C	2/9/2024
		230906E	2/11/2024
		230906H	2/11/2024
		230830E	2/4/2024
		230824E	2/8/2024
230831L	2/9/2024		
00027430011	08426950481058	230817H	1/28/2024
		230831F	2/8/2024
		230906H	2/11/2024
		230831G	2/8/2024
		230830L	2/7/2024
		230828L	2/14/2024
		230830M	2/7/2024
		230831H	2/9/2024
		230822G	2/4/2024
		230831L	2/9/2024
		230824K	1/28/2024
		230824L	1/28/2024
		230825D	1/28/2024
230911M	2/16/2024		

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Part No.	UDI	Lot No.	Expiration Date
00027445011	08426950485711	230822H	2/1/2024
		230901C	2/9/2024
		230818I	1/28/2024
		230821K	2/7/2024
		230830L	2/7/2024
		230831K	2/9/2024
		230828L	2/14/2024
		230824J	1/28/2024
		230821I	2/7/2024
		230818H	2/2/2024
		230823C	2/1/2024
		230824L	1/28/2024
		230908G	2/15/2024
		230824K	1/28/2024
		230817C	1/11/2024
00027360011	08426950485698	230824H	2/3/2024
		230821K	2/7/2024
		230824E	2/8/2024
		230824J	1/28/2024
		230830I	2/9/2024
		230831E	2/8/2024
		230828L	2/14/2024
		230825K	2/2/2024
230911A	2/14/2024		

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.

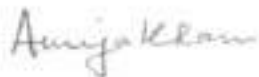
• **Mandatory Customer Actions**

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,



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				

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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		
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		

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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		

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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		

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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		

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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		

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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		

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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
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		

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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		

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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		

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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		

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Part Number	UDI	Lot No.	Expiration Date
00055445008	08426950807797	230824E	2/12/2024
		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
00055445010	08426950807810	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		

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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		

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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