

Legal Manufacturer: Radiometer Medical ApS Åkandevej 21, 2700 Brønshøj, Denmark

Telephone: +45 38 27 38 27

Customer Hospital City Postal code Country Attn.: XXX

ABL800 Basic and ABL8XX FLEX analyzers - Risk of biased out-of-specification pH results

Dear Customer

This is a follow-up to the communication distributed in May 2024, March 2025, and May 2025.

Conclusion for analyzers running with Windows XP (and, hence, software versions below V6.20 MR2)

Radiometer has completed the investigation and is implementing a permanent countermeasure via a supplement to the Operator's manual for analyzers running with Windows XP.

Please note that Microsoft no longer supports Windows XP.

Supplement to Operator's manual

Radiometer has released a "Supplement to the ABL800 FLEX and BASIC Operator's manual for analyzers running Windows XP" to anchor the procedures previously communicated in May 2024. Please see the attached PDF.

Please note that the order of the procedures and the wording in the supplement have been modified compared to the previous communication.

The highlighted text may be rephrased or deleted depending on the distribution method, local regulation, and availability of printed copies:

If you would like to receive printed copies of the supplement, please do not hesitate to contact your Radiometer representative.

Your actions

Radiometer requests that you continue using one of the manual procedures now provided in the "Supplement to the ABL800 FLEX and BASIC Operator's manual for analyzers running Windows XP".

Please complete the Recall Response Form on page 3 of this letter and submit it to your Radiometer representative within two weeks of receiving this letter.



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Your help is appreciated

If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end-user.

If you have any questions, please contact your Radiometer representative.

Radiometer sincerely apologizes for the inconvenience this situation may cause you.

Best regards, <Radiometer distributor>



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Recall Response Form

Conce	erning:			
		and ABL8XX FLEX analyzers ed out-of-specification pH results		
		ve received the customer advisory letter and the "Supplement to the ABL800 FLEX BASIC Operator's manual for analyzers running Windows XP".		
	Furthermore, I confirm that we will continue to use one of the manual procedures now released separately as a supplement to the Operator's manual.			
Hospital Name:				
Your Name:				
Date:				
Signature:				
Ema	ail Address:			