MEDICAL DEVICE RECALL NOTIFICATION

URGENT FIELD SAFETY NOTICE
OSMOPRO® MAX AUTOMATED OSMOMETER
FSCA identifier: 2024-01
Dated: 11 March 2024

Dear Customer,

The purpose of this letter is to advise you that Advanced Instruments, LLC is voluntarily issuing a new Field Safety Corrective Actions (FSCA) for the **OsmoPRO® MAX Automated Osmometer**, Part Number: OsmoPRO MAX (the "Device"), which provides osmolality measurement of serum, plasma, and urine, and is intended for use by trained healthcare professionals.

Reason for the Voluntary Recall:

Advanced Instruments is issuing a recall for the Device due to two issues:

1) System error messages that may delay the ability to test patient samples

2) The need for frequent calibration due to results outside the expected range when testing controls.

Based on internal testing, Advanced Instruments evaluated Device complaints from some customers of sample pre-freeze error messages and other system error messages on the Device that may occasionally delay the ability to test patient samples. Delays in osmolality testing and result reporting may, in turn, cause a delay in a patient diagnosis reliant on an osmolality result. No complaints resulted in Serious Incidents.

Advanced Instruments also received complaints from some customers that tests of a control sample with a known osmolality were outside the expected range more frequently than specified. In accordance with proper procedures, results on a control outside the expected range are remedied by Device recalibration. Adherence to the Device user guide and lab protocol will significantly reduce the possibility of an inaccurate result on a patient sample. Reliance on an inaccurate result may contribute to the rare possibility of an incorrect clinical decision in regard to a certain osmolality result. We are unaware of any inaccurate results of a clinical patient sample and no complaints resulted in Serious Incidents.

How to recognize that the device may fail to consistently perform properly:

- Need for frequent calibration due to control results outside the expected range
- Frequent or repeated error messages
- Two or more consecutive calibration failures

Actions to be taken by the Customer/User:

1. Discontinue use of your device immediately.
2. Advanced Instruments will contact you regarding the return and exchange of your Device. Several solutions are available as needed to ensure continuity of testing.
3. For those users whose lab protocol requires the review of previous data, Advanced Instruments is available to review the data.
4. Complete and return the attached acknowledgement form as soon as possible.

Advanced Instruments
Two Technology Way Norwood, Massachusetts 02062, USA
T: 781-320-9000 Toll Free: 800-225-4034
www.aicompanies.com

Product and Distribution Information:

Product Name, Unique Device Identifier	Manufacturer's Product Number/ Catalog Number	Lot/Serial Number	Manufacturing/ Distribution Dates	Pictures of Product
OsmoPRO® MAX Automated Osmometer **UDI: 00816068021150**	OsmoPRO MAX	All serial numbers that end in "A"	All	

Type of Action by the Company:

Advanced Instruments is implementing permanent corrective actions to address the two issues described and as part of the process above you will be provided with information on the next steps to implement a solution for impacted devices.

Transmission of this Urgent Field Notice:

Please communicate this Field Notice to all those who need to be aware of it within the organization. Additionally, please communicate this notice to any organization where the affected product has been transferred or transfer this notice to other organizations where this action has an impact.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersigned confirms that the relevant Competent Authorities have been advised of this Field Safety Notice, as applicable.

If you need any further information or support concerning this issue, please contact TechService@aicompanies.com. To better assist you, please have your instrument serial number ready.

+1-781-320-9000

Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time.

Sincerely,

[redacted]

Sam Murray

Director, Regulatory Affairs and Quality Assurance

ACKNOWLEDGEMENT FORM

PLEASE COMPLETE AND RETURN THIS FORM

OSMOPRO® MAX AUTOMATED OSMOMETER RECALL

FSCA Number: 2024-01

Dated: 11 March 2024

Date: _____

Recipient Name: _____ Title: _____

Business Name: _____

Address: _____

I certify that I am authorized to sign this Acknowledgement Form on behalf of my organization

Best Contact

Name: _____ Title: _____

Email: _____

Please check the following:

☐ I have read the attached Notification and understand the instructions that I am given.

Signature: _____

Phone Number/Email (optional):_____

SCAN AND E-MAIL SIGNED FORM TO: airegulatory@aicompanies.com

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