Urgent Field Safety Notice

Alere INRatio®/INRatio®2 PT/INR Monitoring System

FSCA-identifier: IVD16.059
Type of action: Device Removal

Date: 18 August, 2016

Dear Valued Customer,
We wish to inform you that Alere San Diego, Inc. is initiating a voluntary removal of the Alere INRatio®/INRatio®2 PT/INR Monitoring System from the market. This removal includes both the Alere INRatio®/INRatio®2 PT/INR Monitors as well as Alere INRatio® /INRatio®2 Test Strips used with the monitors.

What does this mean for you?
Alere recommends that you consult with your healthcare provider as soon as possible to transition to an alternate method of PT/INR testing. After transitioning to another method, we request that all Alere INRatio® monitors and unused test strips be disposed of, either by you or by sending them back to Alere, Inc. Please read this letter carefully to understand how this should be done.

Our records indicate that you have received at least one Alere INRatio® or Alere INRatio®2 PT/INR Monitoring System manufactured by Alere San Diego, Inc.

Details on affected devices:
The following devices/part numbers are affected:

Alere INRatio® Prothrombin Time PT Monitoring System	0100007	Monitor
Alere INRatio®2 PT/INR Home Monitoring Kit	0200432 0200433	Monitor
Alere INRatio® PT/INR Test Strips (Self-Test & Professional Use)	0100071 0100139	Strips
Alere INRatio® 2 PT/INR Test Strips Heparin Insensitive (Self-Test & Professional Use)	99007G1 99007EU 99008G1 99008EU	Strips

Description of the problem:

In December 2014, Alere initiated a voluntary correction to inform users of the Alere INRatio® System that patients with certain medical conditions should not be tested with the system due to the potential, in certain cases, of the Alere INRatio® system to provide an INR result that was significantly lower than a result obtained using a laboratory INR system. As part of its commitment to ensuring the safety of patients, Alere proactively reported this device concern to the U.S. Food and Drug Administration (the "FDA") and other regulators worldwide and began conducting a thorough investigation into these events.

Alere has recently decided to voluntarily remove the Alere INRatio® System from the market and to discontinue manufacturing the product line. Alere will continue manufacturing and distributing the Alere INRatio® Test Strips for a period of time to allow patients to safely transition to another monitoring method.

Alere's focus, as always, is on the safety of patients. **Alere recommends that you consult with your healthcare provider as soon as possible to transition to an alternate method of PT/INR testing**. Alternate methods may include a plasma-based laboratory INR method or monitoring using a point-of-care system from a different manufacturer.

Until you have safely transitioned to an alternate method, you should continue to use the Alere INRatio® System. Inaccurate results may occur if you have certain medical conditions or do not follow the instructions and precautions in the product instructions for use and/or user guide. Please ensure you are testing in accordance with the precautions and recommendations found in the Medical Device Correction notification of December 2014 and current product instructions for use and/or user guide. These are available for review and/or download at http://www.alere.com/en/home/support/inratio-voluntary-withdrawal.html.

Actions we need from you:

1. If you are a current user of the Alere INRatio®/INRatio®2 PT/INR Monitoring System, you should **consult with your prescribing physician/healthcare provider as soon as possible to develop a transition plan to use an alternate method to perform PT/INR testing**. Alternative methods may include a plasma-based laboratory INR method or monitoring using a point-of-care system from a different manufacturer. Until you have transitioned to an alternate method, you should continue to use the Alere INRatio® System.
2. Upon transitioning to an alternate PT/INR testing method, you must:
   - Dispose of all Alere INRatio®/INRatio®2 PT/INR Monitors in your possession in compliance with the instructions in the enclosed Reply Form and document on the form.

   OR

   - Return all Alere INRatio®/INRatio®2 PT/INR **Monitors** in your possession to us. Please contact the Alere INRatio® Support Centre (see the contact details at the end of this letter) for further details on how to do this. Prior to shipment of monitor(s), please clean your device following the Cleaning Instructions in your User Guide.

   AND

   - Dispose of all unused Alere INRatio® /INRatio®2 Test Strips in your possession and document on the enclosed Reply Form. Alere recommends that you cut the test strips prior to disposal.
3. Please confirm that you have read, understood, and will follow the instructions listed above by completing and returning the enclosed Reply Form within 10 business days. You may return the form by fax or e-mail, as instructed below.

Please return the response via air mail in the enclosed postage-paid envelope or fax or e-mail the completed Reply Form to:

Alere INRatio® Support Centre

Fax: +35391680076

Email: EMEproductsupport@alere.com

Transmission of this Field Safety Notice:
If you have passed the meter on to someone else who might be affected by these actions, please pass this notice on to them.

Please keep this notice available until you have completed all of the required actions.

Contact reference:

All relevant National Competent Authorities have been advised of this field safety corrective action. Should you have any questions about the information contained in this notification, please contact:

Alere INRatio® Support Centres

Country	Phone	E-Mail Address
Ireland	+44 161 483 5884 Option 3	EMEproductsupport@alere.com

In Germany, you may also contact our European Representative:

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Tel.: +49 511 6262 8630
Fax: +49 511 6262 8633

Alere sincerely apologizes for any difficulty that this product removal may cause to you. We greatly value our relationship with you. We appreciate your attention and timely cooperation in this matter.

Sincerely,

Rodney D. Mell
Vice President of Quality Assurance and Compliance
Alere San Diego, Inc.

Please complete this form even if you do not have any involved product and mail using the enclosed postage-paid envelope, fax back to fax number +35391680076 or email to EMEproductsupport@alere.com.

URGENT FIELD SAFETY NOTICE REPLY FORM

I have been notified by Alere San Diego, Inc. of the removal of the Alere INRatio®/INRatio®2 PT/INR Monitoring System.

Please check the appropriate boxes:

☐ I have never received this product or have already transitioned to another method of PT/INR testing and therefore will take no further actions.

☐ I have read the letter and confirm that I have transitioned or will safely transition to an alternate method of PT/INR testing upon consultation with my healthcare provider.

Alere INRatio®/ INRatio®2 PT/INR Monitors

☐ **Monitor Disposition (disposal)**: I confirm that I have disposed or will dispose of all monitors to a local, electronic hazardous waste facility or by delivering the Alere INRatio®/INRatio®2 PT/INR Monitors in my possession to another approved disposal facility based on regulations in my local jurisdiction.

Product	Serial Number(s)	Quantity Disposed of
Alere INRatio®/INRatio®2 PT/INR Monitor		

☐ **Monitor Disposition (return)**: I confirm that I have returned or will return all Alere INRatio®/INRatio®2 PT/INR Monitors in my possession to Alere . I have contacted or will contact the Alere INRatio® Support Centre for further information on return instructions.

Product	Serial Number(s)	Quantity to Return
Alere INRatio®/INRatio®2 PT/INR Monitor		

Alere INRatio®/INRatio®2 PT/INR Test Strips

☐ I confirm that I have disposed of or will dispose of the following quantity of Alere INRatio®/INRatio®2 PT/INR Test Strips and/or kits in my possession. (If you do not currently possess any of test strips listed, please indicate zero (0) in the "Quantity Disposed of" field below):

Product	Strip Lot #(s)	Quantity Disposed of	Units
Alere INRatio® /INRatio®2 PT/INR Test Strips			12 Pack Kits
			48 Pack Kits
			Individual Strips

☐ I have read, understood, and have implemented the actions listed above.

Please complete the following information:

DATE:			
SIGNATURE:			
PRINT NAME:			
ADDRESS:			
CITY and REGION		**PHONE:**	
POSTAL CODE:		**COUNTRY:**	
EMAIL:			

Please fax the completed form to the Alere INRatio® Support Centre at +35391680076, email a PDF to EMEproductsupport@alere.com or return the completed form in the pre-paid return envelope.

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt.