Urgent Field Safety Notice

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

FSCA-identifier: IVD16.059

Type of action: Device Removal

Date: 16th August, 2016

Dear Valued Customer,

The purpose of this notification is 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 that collectively constitute the "Alere INRatio® System."

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® PT/INR System Professional	0100004	Monitor
Alere INRatio® Prothrombin Time PT Monitoring System	0100007	Monitor
Alere INRatio®2 PT/INR Professional Testing Kit	0200431	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. Alere identified this issue through internal investigations associated with the recall of the Alere INRatio®2 PT/INR Professional Test Strip in April 2014, which was initiated based on 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 these device concerns 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 patients have periodic verification of their INR using a laboratory INR method. Any patient having significant discrepant low results on the Alere INRatio®/INRatio®2 system as compared to the plasma-based laboratory INR method should immediately be transitioned to an alternate method for monitoring their INR. Significant discrepancy in INR results may lead to a delay in an urgent medical decision to reverse a supratherapeutic INR level, particularly when the erroneous INR result is within the therapeutic range but the actual value is supratherapeutic, i.e., when the actual INR value is 6 or greater. For example, discrepancies in which the laboratory INR value is 6 or greater and the Alere INRatio® INR value is 3 or less are of particular concern. In such cases, actions should be taken not only to reverse the high INR, but also to transition the patient from the Alere INRatio® system to an alternative INR monitoring method. You may also consider discrepancies of a lower magnitude to be significantly discrepant, including discrepancies of 1 or 2 INR units compared to the laboratory INR value, based on your professional judgment and medical practice.

Until such time that your facility has transitioned to an alternate method of PT/INR testing, you should continue to use the Alere INRatio® System as long as you ensure that you and your patients (either patients being tested at your facility or your patients who self-test at home) adhere to the precautions and recommendations found in the Medical Device Correction Notification of December 2014 and current product insert labeling. These are available at http://www.alere.com/en/home/support/inratio-voluntary-withdrawal.html.

Action to be taken by the user/distributor:

- Customers/patients who currently have one or more Alere INRatio®/INRatio®2 PT/INR Monitoring Systems should **transition as soon as possible to an alternate method to perform PT/INR testing**, such as a plasma-based laboratory INR method or a point-of-care monitoring system from a different manufacturer.
- After transitioning to an alternate PT/INR testing method, customers must:

  (Option A) Dispose of all Alere INRatio®/INRatio®2 PT/INR **Monitors** in your possession in compliance with the instructions set forth in the enclosed Reply Form.

  OR

  (Option B) Return all Alere INRatio®/INRatio®2 PT/INR **Monitors** in your possession to Alere. 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.

- You must ensure that you and your staff have read, understood and implemented the actions listed above.
- If you have forwarded product to other customers, please provide a copy of this letter to them.
- Please **complete and mail, fax or e-mail the enclosed Reply Form within 10 business days** to confirm your receipt of this notice.

Please return the response via 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:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please send this notice to any other organisations or customers on which this action has an impact.

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

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 Centre

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 the difficulty that this action may cause to you and your facility. 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 no record of receipt of this product and therefore will take no further actions.

☐ I have read the letter and confirm that users of the Alere INRatio®/INRatio®2 PT/INR Monitoring System in my/my facility's possession have transitioned or will safely transition to an alternate method of PT/INR testing upon consultation with their 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 route 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®2PT/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:			
AUTHORIZED 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.