URGENT: Field Safety Notice
For Patient Self-Testers

Alere™ INRatio® PT/INR Monitor System

December 10, 2014

Dear Valued Customer,

This letter contains important information concerning the Alere™ INRatio® PT/INR Monitor system (INRatio®/ INRatio®2 Monitors and the INRatio®/INRatio®2 Test Strips) that has been prescribed to you for monitoring your blood clotting time (PT/INR) while you are on anticoagulant therapy. A complete list of the affected INRatio® product numbers is attached to this notice (Appendix A). You should discuss this information with your doctor.

In certain cases, an INRatio® PT/INR Monitor system may provide an INR result that is significantly lower than a result obtained using a laboratory INR system. The plasma-based laboratory INR method is considered the most accurate and reliable INR method.

This issue can arise if you have certain medical conditions. The INRatio® PT/INR Monitor system should NOT be used if you have any of the medical conditions listed below. **You should contact your doctor to determine if any of these medical conditions apply to you:**

- Anemia (low hemoglobin or low red blood cell count). Your hematocrit should be between:
  - 30% to 55% for the Alere INRatio® PT/INR Test Strips
  - 25% to 53% for the Alere INRatio®2 PT/INR Test Strips, Heparin Insensitive
- Any conditions associated with elevated fibrinogen levels (Note: fibrinogen is the protein from which a clot is formed)
  - acute inflammatory conditions (for example viral or bacterial infections such as pneumonia or flu)
  - chronic inflammatory conditions (for example rheumatoid arthritis, Crohn's disease, ulcerative colitis, infectious liver diseases such as hepatitis, or inflammatory kidney diseases such as diabetic nephropathy and glomerulonephritis)
  - severe infection (for example sepsis)
  - advanced stage cancer or end stage renal disease requiring hemodialysis
- Any bleeding or unusual bruising

If you have any of these conditions your doctor should immediately switch you to a laboratory INR method for monitoring your INR and anticoagulant therapy. If you are unsure whether you have one of these conditions, you should consult your doctor.

Incorrect results can also occur if you do not carefully follow the instructions for performing the test. Please ensure you take the following precautions to reduce the risk of this issue occurring:

- If your INRatio® INR result falls within the therapeutic range, but you have symptoms of delayed clotting such as bleeding or bruising, you should consult your doctor immediately and arrange for testing by an alternate method.
- Only use the Alere INRatio® PT/INR Monitor system if your hematocrit is within a range of 30% to 55% (Alere INRatio® PT/INR Test Strips) or 25% to 53% (Alere INRatio®2 PT/INR Test Strips, Heparin Insensitive). **You should contact your doctor to arrange for a hematocrit measurement (a red blood cell anemia test)**

if such a test has not been recently performed or there are any signs or symptoms of blood loss.

- Apply **ONLY** one large drop of blood immediately to the test strip. Never add more blood to a test strip after the test has begun. Applying additional sample may result in a discrepant result. **If in doubt, repeat the test with a fresh drop of blood from a new fingerstick site using a new lancet on a fresh test strip**.
- The monitor should be on a stable surface during the test. Do not move the monitor during the test.

In addition to the precautions described above, Alere recommends that you **arrange with your doctor to have your INR measured using a laboratory INR method.** The plasma-based laboratory INR method is considered the most accurate and reliable INR method. Your doctor will adjust your anticoagulant therapy if necessary at this time according to the degree of the difference between the Alere device and laboratory method. Also your doctor has received a notification to investigate whether you have any of the conditions that can lead to these falsely low INR results. Testing is recommended to ensure you do not have conditions that could result in the INRatio® PT/INR Monitor system giving a result that is much lower than the laboratory INR method. If a much lower result is observed, your doctor should immediately switch you to an alternative method for monitoring your INR and anticoagulant therapy.

As part of its commitment to ensuring the safety of patients, Alere has reported these device concerns to the U.S. Food and Drug Administration and other regulatory agencies throughout the world and is conducting a thorough investigation into these events.

Customers with questions regarding this issue can call Alere via the phone number provided in Appendix B depending on your country or origin.

Adverse events or quality problems experienced with the use of this product may be reported to your country competent authority or other agency as required.

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

Alere San Diego, Inc.
9975 Summers Ridge Road
San Diego, CA 92121, U.S.A.
Phone: See Appendix B
E-mail: alere4319global@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

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CUSTOMER REQUIRED ACTION

- **Ensure you have discussed this letter with your doctor**.
- Ensure you have read and understand the precautions described in the current product labelling (Alere INRatio® PT/INR Test Strip Package Insert; Alere INRatio®2 PT/INR Test Strips, Heparin Insensitive; Alere INRatio®2 PT/INR Home Monitoring System User Guide; INRatio® Self Test User Guide) and the additional precautions in this notice describing medical conditions that may increase the risk of obtaining a lower than expected INR result. Note: if you need an additional copy of the product labelling, please contact your local Alere Technical Services Representative.
- Do not use the INRatio® PT/INR Monitor system (INRatio®/ INRatio®2 Monitors and the INRatio®/INRatio®2 Test Strips) if you have any of the medical conditions described in this notice.
- **Speak to your doctor about performing a hematocrit measurement (red blood cell anemia test) and periodic comparisons with a laboratory INR method.**
- Please complete the enclosed Reply Form (Appendix C – the last page of this notice) and **return it within 10 days** to confirm receipt of this notice, using one of the following methods:
    - Return the response via post using the fee paid envelope

      OR
    - E-mail the response to **alere4319global@stericycle.com**
- If you have questions regarding this notice, please call Alere per the appropriate phone number provided in Appendix B.

We appreciate your attention and cooperation in this important matter.

Sincerely,

Keith McLain, VP Quality Alere San Diego

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Appendix A: Product List

Product	Product Part Number	Brand Name
INRatio® Test Strips	0100071	Alere INRatio® PT/INR Test Strips, Box of 12
	0100139	Alere INRatio® PT/INR Test Strips, Box of 48
INRatio® 2 Test Strips	99007EU	INRatio®/ INRatio®2 Prothrombin Time (PT) Test Strips Heparin Insensitive, Box of 12
	99007G1	Alere INRatio®2 PT/INR Test Strip, Heparin Insensitive, Box of 12
	99008EU	INRatio®/ INRatio®2 Prothrombin Time (PT) Test Strips Heparin Insensitive, Box of 48
	99008G1	Alere INRatio®2 PT/INR Test Strip, Heparin Insensitive, Box of 48
INRatio® Monitors	0100004	Alere™ INRatio® PT/INR System Professional
	0100007	INRatio® Prothrombin Time (PT) Monitoring System
INRatio® 2 Monitors	0200431	Alere™ INRatio®2 PT/INR Professional Testing System
	0200433	Alere™ INRatio®2 PT/INR Home Monitoring System

If you would like to receive an additional copy of the labelling for your product, please contact your local Alere Technical Services Representative.

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Appendix B: Country Specific Contact Phone Numbers

Please contact us per the phone number provided below depending on your country of origin:

Country	Phone Number
Austria	**0800-802023**
Belgium	**0800-265-62**
France	**0800-911164**
Germany	**0800-181-7993**
Ireland	**1-800-550-264**
Italy	**800-129-361**
Netherlands	**0-800-022-4656**
Spain	**900-804956**
Switzerland	**0800-554-330**
UK	**0-800-088-5527**

For all other countries please contact your local Alere Technical Services Representative.

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Appendix C: Reply Form

Please complete this form even if you do not have any involved product and Return it via the enclosed postage paid envelope OR email to alere4319global@stericycle.com.

URGENT MEDICAL DEVICE NOTIFICATION: REPLY FORM

I have been notified by Alere San Diego of the precautions for the Alere™ INRatio® PT/INR Monitor system.

Please check the appropriate boxes:

- ☐ I have no record of receipt of this product and therefore will take no further actions.
- ☐ I no longer use this product and therefore will take no further actions.
- ☐ I have read and understand the letter and will follow the recommended precautions and actions. I will discuss this notice with my physician or healthcare provider.

Please complete the following information:

DATE: _____

AUTHORIZED SIGNATURE: _____

PRINT NAME: _____

ADDRESS: _____

CITY: _____ COUNTRY: _____ PHONE: _____

POSTAL CODE: _____ _____

EMAIL: _____

Please return this form using the enclosed postage paid envelope OR email a PDF to alere4319global@stericycle.com

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