U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Alere Recalls INRatio® and INRatio2® PT/INR Monitoring System Due to Incorrect Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Device and Discontinuation of the Product line

- Alere plans to remove the INRatio® and INRatio®2 PT/INR Monitoring System, which includes the INRatio® or INRatio2® PT/INR Monitor and the INRatio® Test Strips, from the market and discontinue manufacture of the product line
- All serial and lot numbers: 0100071, 0100139, 99007EU, 99007G1, 99007G3, 99007G5, 99007G7, 99008EU, 99008G1, 99008G3, 99008G5, 99008G7, 0100004, 0100007, 0100137, 0200431, 0200432, 0200433, 0200457, 55128A
- Manufacturing and distribution dates: Monitor distribution from April 1, 2008; Test Strip kits distributed from April 1, 2008 to July 8, 2016
- Complete **list of affected devices (http://www.inr-care.com/ww/index/healthcare-professional/product-list.html)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- Devices recalled in the U.S.: 125,5765 Test Strip kits (12 count), 24,783 Test Strip kits (48 count), 236,345 INRatio® or INRatio2® Monitors

Device Use

The INRatio® and INRatio®2 PT/INR Monitoring Systems (hereafter referred to as INRatio System), which include the INRatio® or INRatio2® PT/INR Monitor and the INRatio Test Strips, are handheld devices used to monitor blood clotting time as measured by PT/INR values in people taking warfarin (also known by the brand name Coumadin®). The system is intended for both health care professional and home use.

Reason for Recall

Under certain conditions, the INRatio System may generate an incorrect low result; an INR result that is lower than the result expected using a plasma-based laboratory INR method. If an incorrect low INR result is acted upon (i.e. adjusting the dose), the patient may be at risk of major or fatal bleeding. This issue can occur if the patient has certain medical conditions or if the instructions for performing the test are not followed. Alere was unable to develop an adequate modification that ensured the safety and effectiveness of the INRatio System.

Who May be Affected

- People taking warfarin who self-test at home or who are monitored by a health care professional using the INRatio System
- Health care providers who use the INRatio System to monitor patient blood clotting time
- Device retailers
- Device distributors

What to Do

Alere provided the following recommendations:

Consumers with the INRatio System:

Consult with your health care provider as soon as possible to transition to an alternate method of PT/INR testing, such as a point of care monitoring system from a different manufacturer or a plasma-based laboratory INR method.

Patients should:

- Continue to use your current INRatio system until you have safely transitioned to an alternate method.
- Ensure that you perform the test following the precautions and recommendations found in the Medical Device Correction Notification of December 2014 and current product insert labeling.

Health Care Providers should:

- Ensure that your patients transition to an alternative method as soon as possible.
- During the transition, conduct periodic verification of patient INR levels using a plasma-based laboratory INR method. Any patient with significant discrepant low results on the INRatio System as compared to the plasma-based laboratory INR method should immediately be transitioned to an alternate method for monitoring their INR.
- Continue to use the INRatio® System until your patients have safely transitioned to an alternate method of PT/INR testing. Ensure that you and your patients (either patients being tested at your facility or 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.

Retailers and Distributors

- Continue manufacturing and distributing the INRatio Test Strips for a period of time to allow patients to safely transition to another monitoring method.

Alere communicated this information to its customers in an **Urgent Medical Device Recall letter (http://www.inr-care.com/ww/index/healthcare-professional.html)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** on July 26, 2016.

Contact Information

Customers with questions may contact the Alere INRatio Recall Hotline at 866-723-2535.

Date Recall Initiated:

July 11, 2016

Full List of Affected Devices:

Alere INRatio2 PT/INR Professional Monitoring System (55128A)
Alere INRatio2 PT/INR Home Monitoring System (0200432)
Alere INRatio2 Replacement Monitor (Home) (0200457)
Alere INRatio2 PT/INR Professional Testing System (0200431)
Alere INRatio/INRatio2 PT/INR Test Strips (99007EU, 99007G1, 99007G3,99007G5, 99007G7, 99008EU, 99008G1, 99008G3, 99008G5,99008G7)
Alere INRatio PT/INR System Professional (0100004)
Alere INRatio Prothrombin Time (PT) Monitoring System (0100007)
Alere INRatio Replacement Monitor (0100137)
Alere INRatio PT/INR Test Strips (0100071, 0100139)

Additional Resources:

- **Alere INRatio® and INRatio®2 PT/INR Monitor System Voluntary Withdrawal website (http://www.inr-care.com/) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Alere press release for this recall (/Safety/Recalls/ArchiveRecalls/2013/ucm426166.htm)**

How Do I Report a Problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm)** either online, by regular mail or by fax to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)
2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)
2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)
2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)