

# HemoSense<sup>®</sup>...

## ADDITIONAL EXPLANATION TO THE PRODUCT INSTRUCTIONS for Patients using the INRatio Self Test System July 24, 2006

---

Dear INRatio user,

The purpose of this letter is to call your attention to and clarify information that you may have overlooked contained in the INRatio Package Insert regarding the importance of taking appropriate action if you obtain unusual results with your INRatio system.

Your Test Strip Package Insert states:

"If results are unusually low or high, repeat the test. If the results still do not match the clinical situation, test by another method."

### What to do when you get an unusual or unexpected result?

If your result is outside your therapeutic range, follow your doctor's instructions for reporting a high or low INR result outside your range.

If your result continues to be outside your range or does not change after your dose has been adjusted, contact your doctor immediately. Your doctor may arrange for testing of your INR by an alternative method.

If your result is inside your therapeutic range but you have reason to believe your INR could be significantly different (e.g., for example you have symptoms such as bruising or bleeding), call your doctor immediately and arrange for testing by an alternative method.

### What causes unusual or unexpected results?

Unexpected results can be caused by a number of things such as medication and underlying illness. These should be taken into account when your doctor is interpreting your test result.

If you have an underlying disease that affects your hematocrit, i.e., the number of red cells in your blood, (for example anemia or polycythemia), you may have a hematocrit value outside the range recommended for your INRatio system (30 to 55%). Hematocrit readings outside this range may result in inaccurate INR values on your INRatio system. Your doctor may suggest you have a hematocrit test or have your INR tested by an alternative method.

Conditions such as Lupus or antiphospholipid antibody syndrome can falsely prolong your INR regardless of the test system. If you have these conditions, your doctor may suggest testing with a special laboratory test.

As indicated in the Package Insert, other underlying diseases can affect blood coagulation and therefore your INR result. These include liver disease, congestive heart failure, and thyroid dysfunction. Tell your doctor about any disease-specific symptoms you have. Failure to do so may lead to an incorrect interpretation of your INR result by your doctor.

Medications that can affect your INR result include prescription drugs and over-the-counter drugs, such as antibiotics and pain medication. Tell your doctor if you have started, stopped or changed the dose of any medications you are taking. Failure to do so may lead to an incorrect interpretation of your INR result by your doctor.

Additionally, changes in diet or lifestyle and nutritional supplements such as ginseng and ginkgo biloba can affect coagulation and the INR result. Tell your doctor if you are taking a nutritional supplement or have changed your diet or lifestyle. Failure to do so may lead to an incorrect interpretation of your INR result by your doctor.

For additional questions about the INRatio or this letter, call Sysmex UK Ltd on 0870 902 9210 or visit our website [www.hemosense.com](http://www.hemosense.com).