

PRODUCT: Nova Biomedical Ionized Calcium and Ionized Magnesium Sensors

FSN NO: 01-10CCX (Revised 7/2010)

DATE: July 2010

Additional Labeling Instructions

Perchlorate Interference to Mg⁺⁺, Ca⁺⁺ Sensors

Details on Affected Devices:

Nova Biomedical has determined that the chemicals Sodium and Potassium Perchlorate or drugs containing Perchlorate, such as Irenat[®], are sources of interference in the measurement of Ionized Calcium and Ionized Magnesium on the Nova Stat Profile[®] pHox, Stat Profile Critical Care Xpress, the Nova 8 and BioProfile FLEX analyzers.

Description of the Problem:

Our testing indicates that Perchlorate concentrations of 1.0 mmol/L have been shown to **decrease** the reported Ca⁺⁺ concentration by approximately 0.1 mmol/L (0.4 mg/dL) and to **decrease** the reported Mg⁺⁺ concentration by approximately 0.3 mmol/L (0.6 mg/dL).

Advice on Action to be Taken by User:

As a result of this information, Nova Biomedical is requesting your cooperation in inserting this notice in the front of your copy(s) of the Instructions for Use manuals for the Nova Stat Profile pHox, Stat Profile Critical Care Xpress, the Nova 8 and BioProfile FLEX analyzers.

Transmission of this Field Safety Notice:

Please pass this information on to all personnel within your organization who need to be aware of the additional labeling instructions as well as to any organization where the Nova Stat Profile pHox, Stat Profile Critical Care Xpress, the Nova 8 and BioProfile FLEX analyzers have been transferred, if applicable.

The appropriate National Competent Authorities have been advised of this Field Safety Notice.

If you have any questions on this bulletin outside the United States and Canada, contact your local Nova distributor.

Thank you for your continued support of Nova Biomedical products.