

**PRODUCT:** *Nova StatStrip® and StatSensor® Blood Monitoring Systems*

**FSN NO:** *10-13SS-International*

**DATE:** *November 18, 2013*

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## **Nova Biomedical StatStrip and StatSensor Battery Labeling Field Safety Corrective Action**

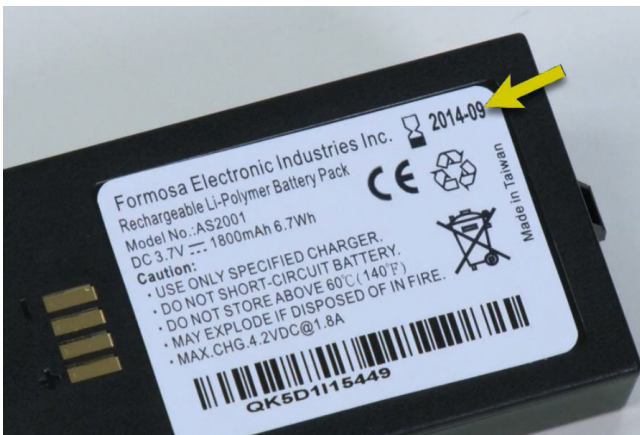
Dear Nova StatStrip and StatSensor Customers,

The Lithium rechargeable batteries used in your Nova StatStrip and StatSensor Hospital Meter Systems are designed to provide the highest level of safety, convenience, quality and durability. However, all rechargeable Lithium batteries have a finite useful life.

This **Field Safety Notice** is to alert users that Lithium batteries utilized beyond their intended useful life may swell and/or crack the external case posing a potential safety hazard. In some cases, the swelling may cause the battery door on the meter to incorrectly seat rendering the meter inoperable. **Nova Biomedical is recalling StatStrip/StatSensor batteries/labels that do not have expiration dates printed on them that help to ensure the batteries are not used beyond their intended useful life.**

Since August 2012, Nova Biomedical has included **expiration dates on the upper right hand corner of the battery label for StatStrip/StatSensor batteries; reference Figure 1. Batteries that exceed their expiration date should be removed from point of use and replaced with a new battery upon receipt of replacement batteries from Nova Biomedical.**

**Figure 1: Battery Label Expiration Date Location**



What to do:

1. Battery Labels **Without** Expiration Dates:

**Nova Biomedical is recalling and replacing all Nova StatStrip and StatSensor batteries without expiration dates on the battery label.** If your institute has not already done so, Nova encourages your institute to immediately implement a battery inspection program to identify and remove batteries from point of use that do not have expiration dates on the battery label. During the inspection, if you identify batteries without expiration dates, please contact Nova Biomedical Technical Support or your authorized local distributor to report this finding and request a no-charge replacement. **Batteries without expiration dates should be removed from point of use and replaced with new replacement batteries received from Nova Biomedical that have expiration dates printed on them.** Batteries removed from point of use should be disposed of in accordance with local regulations.

2. Battery Labels **With** Expiration Dates:

During this periodic inspection, batteries that exhibit any of the following conditions should also be removed from point of use and properly disposed of in accordance with local regulations:

- Swelling
- Cracking or damage to the battery case that is indicative of damage
- Leakage
- Failure to hold a proper charge

If you identify batteries that exhibit any of the above failure conditions, that have not exceeded their expiration date, please contact Nova Biomedical Technical Support or your authorized local distributor to document and report this finding and to request a no-charge replacement of your battery.

If you have any additional questions or concerns or **to arrange for immediate no-charge battery replacements**, in Canada contact us at 800-263-5999, outside N. America contact your authorized local Nova distributor.

We apologize for this inconvenience and thank you for your current and continued support of Nova Biomedical StatStrip and StatSensor products.