

Voluntary Field Correction

We have recently learned that incorrect placement of AA batteries into certain LeadCare® Blood Lead Analyzers may cause the batteries to overheat, and there is a chance that a user could burn their fingers if the batteries are removed while hot.

Description of the Potential Issue

The LeadCare® II and LeadCare Plus® Analyzers are powered either by wall outlet or by four 1.5 V size AA alkaline or lithium batteries. If two of the four AA batteries are inserted incorrectly (the positive and negative ends of the batteries face the wrong directions), the batteries may overheat. This could cause a minor burn if the user opens the battery compartment and tries to remove the batteries while they are hot.

Next Steps

1. Remove the battery cover and follow the instructions and markings for proper battery placement. Batteries should NOT be stored in the analyzer if battery power is not being used.
2. Magellan Diagnostics is sending reminder labels to each customer. Place the label(s) on the upper back panel of the analyzer(s) to remind users who are changing batteries of the importance of correct placement. Change batteries in a well-lit area.



LeadCare® II



LeadCare Plus®

3. Include proper battery placement in annual training and in new user training.
4. A pre-addressed, postage-paid acknowledgment card is included with the labels and should be completed and returned by mail. You can also access a form to be faxed or emailed on our website at www2.magellandx.com/battery. We appreciate you working with us to provide acknowledgement as required by the FDA.

If you have questions, please contact us at 800-275-0102 or reply@magellandx.com.