
Urgent Field Safety Notice

Affected Products: Magellan Diagnostics Inc. LeadCare II Blood Lead Analyzer (Part numbers 70-6760, 70-6529-R, 70-6760-P, 70-6760-R) AND LeadCare Plus Blood Lead Analyzer (82-0001)

Magellan FSCA Identifier : MHRA20180612

Type of action: FIELD SAFETY NOTICE

Date: 18th June, 2018

Attention: **ADD EACH CUSTOMERS DETAILS HERE**

Dear Customer,

We are contacting you to provide important information about a field corrective action regarding the use of LeadCare II and LeadCare Plus blood lead analyzers when used under battery power.

1) Details on affected devices:

All LeadCare analysers:

- LeadCare II Blood Lead Analyzer (Part numbers 70-6760, 70-6529-R, 70-6760-P, 70-6760-R)
- LeadCare Plus Blood Lead Analyzer (82-0001)

See our full Safety Communication at:

<http://www2.magellandx.com/battery>

2) Description of the problem:

The LeadCare II and LeadCare Plus Analyzers are powered either by an AC adaptor or by four 1.5 V size AA alkaline or lithium batteries. The batteries are loaded into a compartment that includes a cover in the back of the analyzer. The compartment is marked to indicate the loading pattern (orientation of positive and negative poles) for each battery. The compartment and cover, like the rest of the analyzer housing, consists of molded plastic.



If two of the 1.5 V size AA batteries are incorrectly inserted in to the LeadCare II or LeadCare Plus Analyzer, the batteries may heat for a period of time due to an increase in current through the batteries. This in turn could lead to thermal injury of the user if they open the battery compartment and try to remove the battery during the heating cycle. This was observed during an internal investigation where a pair of the four batteries were inserted in an order that is reversed from the correct insertion pattern. The worst case for alkaline batteries was a heating cycle of 115.7°C after 5.38 minutes and for lithium batteries was 83.2°C reached for 8 hours and 13 minutes, after which the batteries died and temperature declined.

From January 1, 2012 to the present, Magellan Diagnostics had one incident of a minor user burn reported August 24, 2017, (Complaint number 136863, MDR 1218996-2017-00002). This could not be confirmed as related because the customer was unscrewing the base of the analyzer when the burn occurred, and no additional information was given related to loading the batteries. The burn did not require medical intervention.

Outside of dead batteries or short battery life, the predominant complaints related to batteries during the same time period include battery leakage, rupture, heat, and odor for a rate of 0.34% of all analyzer complaints for that time period, indicating a remote occurrence rate.

The Company has uncovered this potential for a user incident through its investigational process. Although the data indicates the opportunity for occurrence is remote, out of an abundance of caution the Company is initiating a field correction via the Field Safety Notice.

3) Action to be taken by the user:

1).	Ensure that ALL users of LeadCare II Blood Lead Analyzer (Part numbers 70-6760, 70-6529-R, 70-6760-P, 70-6760-R) AND LeadCare Plus Blood Lead Analyzer (82-0001) are made aware of this Field Safety Notice and the correct placement for installing the analyser batteries in the required orientation.
2).	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.
3).	<p>Take the battery warning label which accompanies this Field Safety Notice and affix it to the analyzer(s). Place the label(s) on the upper back panel of the analyzer(s) as shown in the images below, to remind users who are changing batteries of the importance of correct placement. Change batteries in a well-lit area.</p> <div data-bbox="403 853 1264 1279">A photograph of the back of a white and light blue LeadCare II Blood Lead Analyzer. A white warning label is affixed to the upper back panel. The label features a yellow triangle with a black exclamation mark and the text: "WARNING: Incorrect battery placement may cause injury." Below the analyzer, the back panel shows various regulatory markings including a triangle with a lightning bolt, a recycling symbol, "3.3VDC", "FC", and a triangle with a lightning bolt.</div> <p style="text-align: center;">LeadCare® II</p> <div data-bbox="403 1384 1264 1809">A photograph of the back of a grey LeadCare Plus Blood Lead Analyzer. A black warning label is affixed to the upper back panel. The label features a yellow triangle with a black exclamation mark and the text: "WARNING: Incorrect battery placement may cause injury." Below the analyzer, the back panel shows various regulatory markings including a triangle with a lightning bolt, a recycling symbol, "3.3VDC", "FC", and a triangle with a lightning bolt.</div> <p style="text-align: center;">LeadCare Plus®</p>
4).	Include proper battery placement in annual training and in new user training.

5).	<p>Please complete the Acknowledgement form that accompany this Field Safety Notice and return it to Ichor Technologies Ltd. by email, Fax or mail as follows:</p> <p>Email: stuart.naylor@ichortechnologies.com</p> <p>Fax: +44 (0) 1372 388 282</p> <p>Mail: Stuart Naylor Ichor Technologies Ltd 1 Paper Mews Dorking, Surrey RH4 2TU United Kingdom</p>
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4) Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

5) Contacts:

EU Representative Inquiries:

Stuart Naylor
Ichor Technologies Ltd
1 Paper Mews
Dorking, Surrey
RH4 2TU, United Kingdom
Tel: +44 (0) 1372 377 754 Fax: +44 (0) 1372 388 282
Email: stuart.naylor@ichortechnologies.com

Magellan Diagnostic Inc. Regulatory Affairs Inquiries

Heather Reed
Magellan Diagnostic Inc.
101 Billerica Avenue, Building 4
Billerica, Massachusetts
MA 01862, United States of America
Tel: +1 978 248 4811 Fax: +1 978 856 2335
Email: heather.reed@megallandx.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency (The Medical Healthcare products Regulatory Agency [MHRA] in the United Kingdom)

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Stuart Naylor
Ichor Technologies Ltd.
18th June, 2018

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Heather Reed
Magellan Diagnostic Inc.
18th June, 2018

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Replace with Magellan Safety Communication to Customers Record Form
M-0155 Rev01 Magellan EU Fax Back Form

Safety Communication to Customers

FAX/EMAIL FORM RECORD: Notification on LeadCare® Systems

This Acknowledgement Form is intended to verify that you have read and understood the Field Safety Notification regarding the proper installation of LeadCare II and LeadCare Plus batteries. The return of this form is being tracked for regulatory purposes.

Please complete this form acknowledging receipt of the notification and fax or email the signed copy to +44 (0) 1372 388 282 or email stuart.naylor@ichortechnologies.com. In the event of a transmission problem please telephone +44 (0) 1372 388 282.

Part I: Site information for ALL responses

Key Contact Name & Title _____

Email _____ Phone Number _____

Institution Name _____

Instrument & Serial #(s): (i.e., LeadCare II, WLC#####) _____

Street Address _____

City _____ State/Province _____ Zip/Postal Code/Country _____

Part II: Safety Communication to customers using LeadCare II Blood Lead Analyzers (Part numbers 70-6760, 70-6529-R, 70-6760-P, 70-6760-R) AND LeadCare Plus Blood Lead Analyzers (82-0001).

Please verify with a check (√) that the following actions were taken by your facility:

We read, understood and reviewed the Safety Communication with our staff:

- All Users have been made aware of this Field Safety Notice including
 - The instructions and markings for correct placement/installation of the analyser batteries
 - That batteries should NOT be stored in the analyzer if battery power is not being used
 - Batteries/the Analyzer should be charged in a well-lit area.
- Proper battery placement in annual training and in new user training.

We have affixed the battery warning label(s) provided to the upper back panel of the analyzer(s), to remind users who are changing batteries of the importance of correct placement.

OR

We do not own or are not operating a LeadCare analyzer

Signature for ALL responses

Name (please print) _____ Title _____

Signature _____ Date _____

Contact Magellan Diagnostics at +1 978-275-0102 or LeadCareSupport@magellandx.com or Ichor Technologies at +44 (0) 1372 377 754 with any questions

Please fax or email this record back to:
Attention: Stuart Naylor
 Phone No.: +44 (0) 1372 377 754 (for transmission problems only)

Fax: +44 (0) 1372 388 282
Email: stuart.naylor@ichortechnologies.com