August 15, 2016

URGENT: MEDICAL DEVICE CORRECTION

Re: Laerdal Suction Unit (LSU) Cat. No. 78002001 when used with LSU NiMH Battery Cat. No. 780800; All lot numbers sold between December 9, 2013 and July 26, 2016

Attention Risk Manager - Immediate Attention Required!

Dear Laerdal Customer,

The purpose of this Correction Notice is to alert you of a problem that may occur while using the Laerdal Suction Unit (LSU) with the LSU Nickel Metal Hydride Battery (NiMH) when the battery has been stored or installed at temperatures between 0°C and 9°C. Please review the enclosed documents carefully and ensure that all personnel responsible for the storage, maintenance, charging and use of the Laerdal Suction Unit are fully aware of this Notice and enclosed instructional materials. An Addendum to the Directions for Use is also enclosed and it is important that a copy of this be attached to each LSU Directions for Use booklet.

Problem: Following storage at temperatures between 0°- 9°C (32°- 48°F), the LSU with NiMH Battery may shut off after a few seconds when operating at a vacuum level > ~200 mmHg when set to either the 350mmHg or 500+mmHg dial setting. Should this occur, the short-term or interim solution to restore LSU operation is to switch the unit to 0 (Off) then back to a reduced suction level (please refer to detailed enclosures). Laerdal Medical is working on a long-term solution and further information on this will be provided in approximately 90 days.

Laerdal Medical Corporation, New York USA is conducting this correction on behalf of the manufacturer, Laerdal Medical AS, Norway. Stericycle, on contract to Laerdal Medical Corporation, New York, is providing the logistical support for this notice and recording your contact information so that Laerdal can follow up with you. All information furnished by you is protected under our Privacy Policy and Non-disclosure agreement with Stericycle.

Affected Products:
Laerdal Suction Unit (LSU) and LSU NiMH Battery products listed below:
Laerdal Suction Unit (LSU), Cat. No. 78002001; powered by the LSU NiMH Battery. All lot numbers sold between December 9, 2013 and July 26, 2016. Note: LSUs have been shipped with the NiMH Battery since December 9, 2013.
Laerdal NiMH Battery, Cat. No. 780800; all lot numbers sold since December 9, 2013.

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Actions to Take:

1. Assure that all patient care personnel are aware of this Notice and that they understand the implications associated with the potential device shutdown. Review your present emergency operating procedures and check any backup equipment to support a rapid and appropriate response to any unexpected equipment failure. Familiarize all persons who use the LSU with the storage temperature issue potential and the interim instructions Addendum to Direction for Use included with this Medical Device Correction Notice. Keep this Notice with your LSU Directions for Use (DfU) booklet.
2. Confirm receipt of this Medical Device Correction Notice by completing and returning the enclosed Customer Acknowledgement Form-USA to Stericycle. Follow instructions on the form to provide product and follow-up contact information so that Laerdal can contact you with information about the long-term solution.
3. If you are not the LSU end-user; during step 2 above, please identify yourself to Stericycle as a distributor, reseller or donor of the products and furnish all recipient's name(s) and contact information so that they can be sent/receive a direct copy of this LSU Medical Device Correction Notice.
4. Should you have questions related to this Medical Device Correction Notice, please contact:

Stericycle, Inc. reference Event #4409

E-Mail: laerdal4409@stericycle.com
Phone: 877-857-3783
FAX: 877-546-0461

Mail: Stericycle ExpertSOLUTIONS
6026 Lakeside Blvd, Suite A
Indianapolis, IN 46268
ATTN: Event# 4409

For product matters not related to this Medical Device Correction Notice, please contact Laerdal:

Laerdal's Customer Solution Center
E-Mail: customerservice@laerdal.com
Phone: 877-523-7325
FAX: 800-227-1143
Mail: Laerdal Medical Corporation
167 Myers Corners Road
Wappingers Falls, NY 12590

For current LSU product/service updates and other information:
Laerdal Medical Website
www.laerdal.com/us/LSU

This voluntary correction is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA) and is administered by Laerdal Medical with support from Stericycle, Inc., a recognized professional safety notice communications and services provider.

Laerdal regrets and seeks to minimize any inconvenience caused by this correction. Your prompt attention to this Notice will be appreciated. We look forward to contacting you about a long-term solution.

Thank you.

Ronald Weyhrauch
Director, Legal and Regulatory Affairs
Laerdal Medical Corporation, New York 12590 USA

Enclosures: Customer Acknowledgement Form-USA, manufacturer's Dear Customer letter, manufacturer's Urgent Field Safety Notice, and Laerdal Suction Unit-Addendum to Direction for Use

#16-15358

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CUSTOMER ACKNOWLEDGEMENT FORM – USA

IMMEDIATE REPLY REQUESTED

E-mail: laerdal4409@stericycle.com
FAX this form to: 877-546-0461
Mail this form to:
Stericycle ExpertSOLUTIONS
6026 Lakeside Blvd, Suite A
Indianapolis, IN 46268
ATT: Event# 4409

Customer Name: _____ Laerdal Cust#:_____

Address: _____

Address: _____

City, ST, ZIP: _____

Our records indicate you have received:
Qty of Laerdal Suction Units (LSU) provided with a NiMH Battery: _____
Qty of NiMH Batteries (purchased separately): _____

ALL RESPONDEES: PLEASE CHECK ALL THAT APPLY:

__ The above address is correct, or corrections are noted above.

__ We have read, understood and familiarized all LSU users with the instructions provided in the Urgent: Medical Device Correction Notice.

__ We confirm that we have a total of ___ LSUs, and we have a total of ___ LSU NiMH Batteries.

__ Our organization no longer owns or uses Laerdal Suction Units or LSU NiMH Batteries. Our LSUs and NiMH Batteries were _ retired, _ sold, _ donated, _ traded in. Names and contact information of last known owners are listed below* (please use additional pages if necessary).

Completed by: Printed Name: _____ Date:_____

E-mail/Phone Contact#: _____

Signature:_____

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Customer Name: _____ Laerdal Cust #: _____

ALL DISTRIBUTORS: In addition to the above:

__ We have read, understood and will comply with instructions provided in the **Urgent: Medical Device Correction** Notice.

__ We will contact our customers directly and provide them with full copies of the Laerdal Medical Device Correction Notice – USA information package. We will receive and record customer responses, including numbers of LSUs and affected NiMH Batteries, and deliver all details and customer contact information to Stericycle.

__ We will deliver our customer contact list information, including numbers of LSUs and affected LSU NiMH Batteries sold to each customer, to Stericycle for them to complete the Notice instructions on our behalf for Laerdal Medical.

Completed by: Printed Name: _____ Date: _____

E-mail/Phone Contact#: _____

Signature: _____

***Last Known Owner:**

Name: _____

Address: _____

_____

_____

Telephone: ( ) _____

E-mail: _____

***Last Known Owner**

Name: _____

Address: _____

_____

_____

Telephone: ( ) _____

E-mail: _____

ALL RESPONDEES:

For product matters not related to this Medical Device Correction Notice, please contact Laerdal's Customer Solution Center:

E-Mail: customerservice@laerdal.com
Phone: 877-523-7325
FAX: 800-227-1143
Mail: Laerdal Medical Corporation
167 Myers Corners Road
Wappingers Falls, NY 12590

Thank you.

Ronald Weyhrauch
Director, Legal and Regulatory Affairs
Laerdal Medical Corporation, New York 12590 USA

#16-15359