



August 15, 2016

URGENT FIELD SAFETY NOTICE

Laerdal Suction Unit (LSU) when used with the LSU NiMH Battery at low temperatures

Dear Laerdal Customer,

The purpose of this Field Safety Notice package is to alert you to a problem that may occur while using the Laerdal Suction Unit 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 information. An Addendum to the Directions for Use is also enclosed and it is important that this be attached to your Directions for Use booklet.

Laerdal Medical Canada Ltd. is conducting this Field Safety Notice on behalf of the manufacturer, Laerdal Medical AS, Norway. Stericycle Canada, on contract to Laerdal Canada is providing the logistical support for this notice. All information provided by the customer is protected under our Privacy Policy and Non-disclosure agreement with Stericycle.

If you have questions regarding any of the information contained within this Field Safety Notice please contact:

Paula Marsden
Quality Assurance and Regulatory Affairs
Laerdal Medical Canada Ltd.
416 298-9600
Paula.marsden@laerdal.com

This Field Safety Notice has been reported to Health Canada under Section 64 of the Medical Devices Regulations.

Please acknowledge receipt of this Field Safety Notice at your earliest convenience by following the notification instructions provided by Stericycle Canada.

Laerdal Medical regrets any inconvenience caused by this Field Safety Notice.

Sincerely,

Paula M. Marsden, MHSc.
Quality Assurance and Regulatory Affairs,
Laerdal Medical Canada Ltd.

Encl.: Customer Letter (Laerdal Medical AS), Urgent Field Safety Notice (2016-R-01), Laerdal Suction Unit – Addendum to Direction for Use, Instructions - Stericycle Canada.



Business Reply Form – RESPONSE REQUIRED

Upon receipt of the Field Safety Notice, please take the following actions:

- As requested in the attached notification sent via courier on August 15, 2016, please respond by completing the business response form below.

___ I have **NO** affected products in stock.

___ I have affected products (please specify quantities using table below).

All versions of the Laerdal Suction Unit (LSU) shipped with NiMH battery – <i>Serial Number 78451361071 or higher, distributed from November 2013 to present.</i>	Quantity on Hand
78000020 LSU with Reusable Canister (English)	
78000016 LSU with Reusable Canister (French)	
78001020 LSU with Abbott Receptal Canister (English)	
78001016 LSU with Abbott Receptal Canister (French)	
78003020 LSU with Serres Suction Bag Canister System (English)	
78003016 LSU with Serres Suction Bag Canister System (French)	
LSU NiMH Battery – <i>All lot numbers</i> Catalogue Number 780800 LSU NiMH Battery	

IMPORTANT – PLEASE COMPLETE BELOW ALL INFORMATION (LEGIBLE PRINTING):

CUSTOMER NAME	
CUSTOMER ACCOUNT NO	
(SHIP TO account only) NAME OF CONTACT: <i>(for return instructions)</i>	
NAME:	
SIGNATURE & DATE:	

- Please fax or email the completed form by August 26, 2016 to:**
 Fax: 888-714-5073
 Email: laerdal6577@stericycle.com

*This BRF is for single use only, please DO NOT reproduce.
 If you require additional assistance contact Stericycle at 866-912-8410 (M-F 8am to 5pm ET)*