Urgent Field Safety Notice

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

2016-R-01

Field Safety Notice

Date: 15 July 2016

Important Note! This safety notice only applies to Laerdal Suction Units used with NiMH batteries when the core temperature of the NiMH battery gets low, typically between 0 °C and 9 °C (32 °F to 48 °F). This occurs when the LSU with NiMH battery has been stored or installed in cold environments (9 °C or less) for prolonged period.

If the LSU with NiMH battery is normally stored or installed at temperatures above 9 °C, the instructions in this Safety Notice may be disregarded.

Details on affected devices:

- All versions of Laerdal Suction Unit (LSU) when used with NiMH Battery, irrespective of canister type - *All serial numbers*
    - 780000xx LSU with Reusable Canister
    - 780010xx LSU with Abbot Receptal Canister
    - 78002001 LSU with Bemis Canister
    - 780030xx LSU with Serres Suction Bag Canister System

- Laerdal Suction Unit (LSU) shipped with LSU NiMH battery – *Serial Number 78451361071 or higher*
    - 780000xx LSU with Reusable Canister
    - 78002001 LSU with Bemis Canister
    - 780030xx LSU with Serres Suction Bag Canister System

- LSU NiMH Battery - *All lot numbers*
    - Catalogue Number 780800 LSU NiMH Battery

xx signifies the language code:

00 – Norwegian	*07 - French*	*16 – Canadian French*
02 – Swedish	*08 - Finish*	*20 – Canadian English*
03 – English	*09 - Italian*	*29 – Spanish*
04 – Dutch	*10 - German*	*33 – International English*
05 - Japanese	*11 - Danish*	*43 – Polish*

Description of the problem:

The Laerdal Suction Unit (LSU) may shut off when operated at 350 mmHg or 500+ mmHg (46.6 kPa or 66.5+ kPa) settings if the core temperature of the NiMH battery is low, typically between 0 °C and 9 °C (32 °F to 48 °F). For example, this can occur if the LSU is installed in an ambulance parked outside in very cold climates, without heating in the vehicle. It can also occur if the NiMH battery is stored at low temperatures and installed in the LSU immediately before use.

When the core temperature of the NiMH battery is low, and the suction tube is occluded, the ability of the battery to supply power to the LSU at high vacuum settings (350 mmHg or 500+ mmHg, 46.6 kPa or 66.5+ kPa) may be impaired. This may happen because the voltage in the battery drops when the suction tube is occluded to a level where the LSU unit is programmed to shut down.

This can occur when performing suction, or when the Device Test or Battery Quality Tests described in the Directions for Use are being performed.

In the event that the LSU shuts off the unit will not provide suctioning. This may cause a delay in clearing of the patient's airways.

Advise on action to be taken by the user:

Identify affected Laerdal Suction Units:

This Safety Notice covers:

- All Laerdal Suction Units (LSU) with Serial Number 78451361071 or higher, irrespective of canister types (Reusable, Abbot, Serres and Bemis)
- All Laerdal Suction Units (LSU) when used with 780800 LSU NiMH Battery (all serial numbers)

Identify LSU NiMH battery:

The LSU NiMH battery is easily identified by the catalogue number (Cat. No. 780800), and the battery type (NiMH) on the battery label – see illustration below:

Identify if your LSU is likely to be used when the core temperature of the battery is low:

This safety notice applies to LSUs operated with batteries with a low core temperature, e.g., where the LSUs are installed in locations where the temperature may be below 9 °C (48 °F) for a prolonged period such as overnight, or to batteries that are routinely stored at low temperatures immediately before use.

Actions to be taken if your LSU is likely to be used when the core temperature of the battery is low

If the LSU is has been stored or installed in environmental conditions which may result in the core temperature of the battery may fall below 0 °C to 9 °C (32 °F to 48 °F), the unit should be operated at vacuum setting 200 mmHg or below – see table below.

Battery core temperature	*Vacuum setting*				
	80 mmHg (10.6 kPa)	120 mmHg (16 kPa)	200 mmHg (26.6 kPa)	350 mmHg (46.6 kPa)	500+ mmHg (66.5 kPa)
0°C (32 °F)	V	V	V	*	*
5°C (41 °F)	V	V	V	*	*
9°C (48 °F)	V	V	V	V	V
20°C (68 °F)	V	V	V	V	V
30°C (86 °F)	V	V	V	V	V
40°C (104 °F)	V	V	V	V	V

* At these temperatures and vacuum settings, the LSU may shut off after some seconds when partially or fully occluded.

Actions to be taken if your LSU shuts off during use

If the LSU shuts off after short time of use, the user should turn the LSU on again, but with a vacuum setting of 200 mmHg (26.6 kPa) or less, or switch to an alternative suction device.

Actions to be taken to increase the core temperature of the NiMH battery

To increase the core temperature of the NiMH battery inside an LSU, turn on the LSU to the 500 mmHg (66.5+ kPa) setting and run the device at free flow for 10 minutes on battery power.

Recommendations for continued safe use of the LSU

Please note that if the LSU is installed or stored in locations where the temperature is above 9 °C (48 °F) the Laerdal Suction Unit can be operated in low temperatures at all vacuum settings.

Please note that the short-term and long-term storage temperatures stated in the Directions for Use still apply: A battery that has been stored at low temperatures will be fully functional when the battery has been allowed to warm up.

Please Note: the LSU Directions for Use recommend batteries to be charged at ambient temperatures, between 15 °C to 25 °C (59 °F to 77°F).

Always perform the device test described in the Directions for Use to verify that your suction unit operates satisfactorily.

Actions to be taken by Laerdal to mitigate the problem

Laerdal Medical is working on a long-term solution and further information on this will be provided in approximately 90 days.

Transmission of this Field Safety Notice:

Please transfer this notice to other organisations on which this action has an impact, i.e. all staff involved in the storage, maintenance, charging and use of the Laerdal Suction Unit (LSU).

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

Contact reference person:

Anne Lise Eikefjord

QA Manager
Laerdal Medical AS
P.O. Box 377, Tanke Svilandsgate 30
4002 Stavanger
Norway

Anne-Lise.Eikefjord@laerdal.com

Telephone: +47 51 51 17 00