



**Laerdal**

helping save lives  
15 July 2016

Dear Customer

Laerdal Medical has become aware of a problem related to use of the Laerdal Suction Unit (LSU) when used with the LSU NiMH Battery that have **been stored or installed** at low temperatures for a prolonged period. The problem may occur if the LSU with a NiMH battery, or the NiMH battery, has been stored at low temperatures so that the core temperature of the NiMH battery is low, typically between 0 °C and 9 °C (32 °F to 48 °F). If used with a NiMH battery with low core temperature, the LSU may shut off after some seconds when operated at 350 mmHg or 500+ mmHg (46.6 kPa or 66.5+ kPa) settings. **Please note:** If NiMH the battery has been stored at temperatures above 9 °C, and used at low temperatures, use should not be affected. The number of reported incidences related to this problem is low.

Please note that this information is specific to Laerdal Suction Units with NiMH batteries stored or installed at environmental conditions below 9 °C where the core battery temperature gets low.

The intention of this letter and the attachments is to provide you with information about:

- Description of the problem and how it might affect the use of the Laerdal Suction Unit
- Actions to be taken by you as customer
- Addendum to the Directions for Use for the Laerdal Suction Unit
- Actions to be taken by Laerdal Medical

**This document contains important information for the continued safe use of the Laerdal Suction Unit**

*Please review the Field Safety Notice and the Addendum to the Directions for Use with all personnel involved in the storage, maintenance, charging and use of the Laerdal Suction Unit (LSU). It is important to understand the implications of this communication.*

*Please retain a copy of the Field Safety Notice and the Addendum to the Directions for Use.*

Attached to this letter is:

- Field Safety Notice containing instructions of how to identify the affected units, and on the actions to be taken by the customer to ensure continued safe use of the Laerdal Suction Unit (LSU)
- Addendum to the Directions for Use for Laerdal Suction Unit (LSU) with instructions on vacuum setting to be used if the core temperature of the battery is low and how to proceed if the LSU shuts off during use.

If you should have any questions, regarding the problems described in the Field Safety Notice or to the actions to be taken, please contact your local Laerdal Medical representative.

This Field Safety Notice will be reported to the appropriate authorities.

Laerdal Medical apologises for the inconvenience caused by this problem. Releasing products and services of the highest quality is at the root of our mission - helping save lives - and your continued trust in us will always be our top priority.

Kindest regards,

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## **Urgent Field Safety Notice**

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

**2016-R-01**

#### **Field Safety Notice**

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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:**

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