FREQUENTLY ASKED QUESTIONS (FAQS)

Laerdal Suction Unit (LSU) – LSU NiMH Battery (2016-R-01)
Urgent: Medical Device Correction

The following FAQs address general inquiries arising from the recently released Field Safety Notice – Medical Device Correction referenced above. The Notice was sent to customers and contains important information for those who operate or maintain Laerdal Suction Units and LSU Batteries. If the information you seek is not presented herein, please contact Laerdal Medical Customer Support by email for a prompt response (include a brief description of the information needed, plus your name, e-mail address and phone number to facilitate Laerdal's follow-up contact with you).

For United States and Latin America: customerservice@laerdal.com
For Canada: savelives@laerdal.com

Q1. Which LSU items are affected in the Americas?

All versions of Laerdal Suction Unit (LSU) when used with NiMH Battery, irrespective of canister type (LSU Catalog Numbers 780000xx, 780010xx, 78002xx and 780030xx).

Laerdal Suction Unit (LSU) Catalog Numbers 78000016, 78000020, 78002001 and 78003016, 78003020, shipped with NiMH battery.

NiMH Battery Catalog Number 780800 (see illustration below).

Note: LSUs powered by the Lead-Acid Battery, Cat. No. 780400, are not affected by this core temperature issue (refer to Q2 and Q13 below).

Q2. What is the problem?

A root cause investigation has established that when the core temperature of the LSU NiMH battery is lowered, typically to 0 ºC to 9 ºC (32 ºF to 48.2 ºF), the ability of the NiMH battery cells to supply power to the LSU operating at high vacuum levels (on 350 mmHg or 500+ mmHg settings) performance is impaired and the LSU may shut off unexpectedly.

At a vacuum level of 200 mmHg or less, the LSU with NiMH battery will perform per specification regardless of the core battery temperature.

If the LSU with NiMH Battery is being powered from external AC/DC power, its operation will not be affected regardless of battery core temperature.

Q3. How likely is it that LSU operators will experience this issue?

The reported occurrence of the problem is extremely low.

This issue is most likely to happen in EMS services where an LSU with NiMH battery is stored overnight in a vehicle parked in a cold environment, without sufficient supplementary heating (e.g., heating directly to the vehicle itself via an electrical connection, or by being parked in a warmed garage). No complaints have been received from EMS services in warm environments, in-hospital or homecare use.

Q4. What should LSU operators do if they experience this problem while suctioning a patient?

If the LSU with a NiMH battery shuts off suddenly during use, the operator should turn the LSU off and then back on, but with a maximum vacuum setting of 200 mmHg or turn the LSU off and connect external AC/DC power before turning it back on, or use an alternative suction device.

Q5. Will this problem occur when an LSU with NiMH battery is taken from a vehicle at ambient temperature to use on a patient in a much cooler environment?

No, not if the core temperature of the NiMH battery is above 9 ºC (48.2 ºF). Even when removed from the vehicle, the temperature of the battery is unlikely to cool sufficiently for this shut off problem to occur.

Q6. How do LSU operators check if they suspect a fully charged NiMH battery may be affected by temperature and not working according to specification?

Operators should either perform a LSU Device Test as specified in the LSU Directions for use, or turn on the LSU with NiMH battery to 500+ mmHg (66.5 kPa) setting and occlude the patient tubing a number of times. If the LSU shuts off, the battery core temperature is likely to be too low. If the LSU continues to function as intended, the battery can be used without any further actions.

Q7. How do users prevent this problem from occurring?

Users should ensure their LSU with NiMH battery are continuously being recharged, when not in use, at the DFU recommended charging temperatures of 15 ºC to 25 ºC (59 ºF to 77 ºF).

If you change the battery in the LSU, make sure the replacement battery has a core temperature above 9 ºC (48.2 ºF).

Q8. How quickly does a NiMH battery take to warm up from 0 ºC to > 9 ºC (48.2 ºF)?

The core temperature of NiMH battery can be raised from 0 ºC (32 ºF) to 9 ºC (48.2 ºF) by storing the LSU at room temperature for at least 1 hour.

Q9. Is this issue related to the LSU canister system being used?

This issue is independent of the LSU canister system being used.

Q10. How will new LSU customers be made aware of this issue?

All purchasers of new LSUs or the LSU NiMH Battery as a spare part will receive an Addendum to the LSU Directions for Use containing information about temperature limitations, and how to proceed if the LSU shuts off during use. (A copy of the Addendum is included in the Field Safety Notice – Urgent Medical Device Correction documentation package.)

Q11. Will the NiMH battery be damaged from storage at low temperatures?

No. The short-term and long-term storage temperatures stated in the Directions for Use still apply: The NiMH battery can be stored long-term at 0 ºC to 40 ºC (32 ºF to 104 ºF), and for a short term up to 24 hours the battery can be stored at -30 ºC to +70 ºC (-22 º F to 158 ºF). A battery that has been stored at low temperature will be fully functional when the battery has been allowed to warm up.

Q12. How can I know if my battery is a NiMH Battery?

The LSU NiMH Battery is easily identified by the Catalog Number 780800, and the battery type (NiMH) on the battery label – see picture in Q1.

Q13. Will I experience the same problem if I use a different battery (other than Laerdal brand, or different from the NiMH Battery?

The LSU should only be operated with a Laerdal brand battery (or one specifically recommended by Laerdal Medical). The only batteries currently recommended by Laerdal Medical are:

Laerdal Suction Unit – Battery (Lead-Acid), (Catalog Number 780400, manufactured by Laerdal Medical up until 7 November 2013). LSUs with Lead-Acid Battery are not affected by this temperature issue.

LSU NiMH Battery, Catalog Number 780800, distributed in the Americas in LSUs and as a spare part beginning on December 9, 2013.

Q14. When will I receive/Why did I not receive the LSU Urgent Medical Device Correction notice?

Notices marked 'Urgent: Medical Device Correction' were went to Laerdal-direct purchasers (LSU owner/operators and Laerdal distributors) by United Parcel Service (UPS) ground service addressed to the attention of 'Risk Manager'. Notifications were dispatched on August 19, 2016 by Laerdal Medical's contracted notification and follow-up services provider, Stericycle, Inc., located in Indiana.

If you own, operate, maintain or distribute LSUs and LSU Batteries, and have not yet received Laerdal's notification, immediately contact Stericycle.

For United States and Latin America: laerdal4409@stericycle.com
For Canada: laerdal6577@stericycle.com

You will be registered as a person/entity in possession of affected LSU products and a notification package will be sent directly to you.

Note: It is possible that a brief delay in your receipt of the original LSU notification is due to your indirect purchase of LSU goods, e.g., through a distributor, so your Laerdal distributor's notification arrangements through Stericycle may have imposed a brief delay and you may receive more than one notification package as a result. You need only respond to one of the notification packages received.

Q15. I have received and acted upon the LSU Notice as directed. What if I have another LSU question or wish to advise Laerdal Medical of a different issue or matter?

Contact Laerdal Medical's Customer Service directly:

For United States and Latin America: customerservice@laerdal.com
For Canada: savelives@laerdal.com

Your information need or issue inquiry will be followed up and resolved as quickly as possible.

End of FAQs