

URGENT DEVICE RECALL

Date: 3 January 2017

Dear Customer:

This is to inform you of a product recall involving:

Laerdal Compact Suction Units (LCSU4 300 ml) and (LCSU4 800 ml)

manufactured between May 1, 2015 until October 28th, 2016



LCSU4 300 ml (3.3 lbs.) canister version



LCSU4 800 ml (4.3 lbs.) canister version

Details on affected devices:

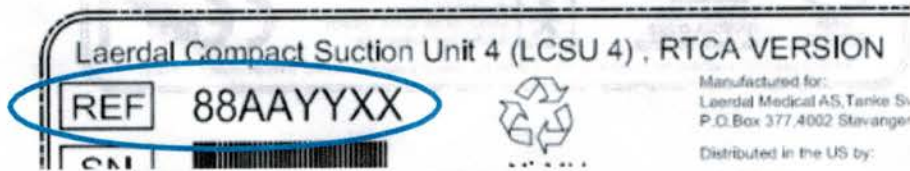
Affected units have the following REF numbers and are labelled with Manufacturing Dates in the range 20150501 to 20161028.

Standard Version:

- 88005101 - LCSU4, 800 ml Complete unit (US)
- 88006101 - LCSU4, 300 ml Complete unit (US)
- 881151 - Replacement unit

RTCA Version (approved for use on aircraft):

- 88005201 - LCSU4, 800 ml, RTCA Complete unit (US)
- 88006201 - LCSU4, 300 ml, RTCA Complete unit (US)
- 881152 - Replacement Unit, RTCA



Description of the problem:

The On/Off functionality in the LCSU4 is controlled by electronic components. One of these components might be damaged. The damage occurs over time when the unit is connected to a power source (battery or external power source), but is not related to frequency of use.

A damaged component will result in failure of the On/Off functionality: The LCSU4 cannot be turned off, and it may turn on by itself.

Typical failure modes are outlined below:

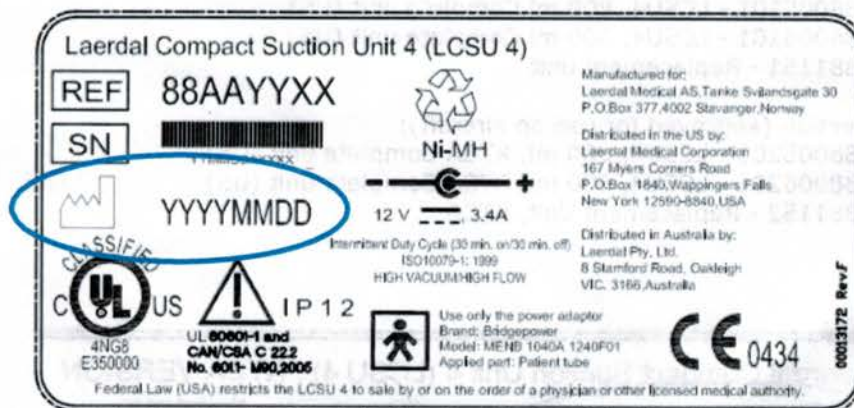
- The LCSU4 turns on by itself. The LCSU4 continues to run until the battery is drained, and the LCSU4 will not operate. If a new battery is inserted, or if the unit is connected to an external power source, the LCSU4 starts running by itself again. When it is running, it is not possible to turn the unit off using the On/Off Button.
- The LCSU4 starts running by itself while connected to an external power source. The LCSU4 cannot be turned off using the On/Off Button.
- The LCSU4 can be turned on using the On/Off button. The LCSU4 cannot be turned off using the On/Off button.

In all of the above failure modes, the unit can be turned off by removing the battery or the external power source.

The LCSU4 units are labelled with Manufacturing Date in the format YYYYMMDD (year - month- day).

Affected units are labelled with Manufacturing Dates in the range 20150501 to 20161028.

The Manufacturing Date can be found on the label on bottom of the LCSU 4 as shown below:



Exception: Some LCSU4 units have a 'RW' label on the bottom. These units have been reworked by Laerdal Medical and are not affected by this Field Safety Notice, even if they have manufacturing dates within the 20150501 to 20161028 range.



Advise on action to be taken by the user:

- Check On/Off functionality:

You can periodically run a quick test to identify if the unit has failing On/Off functionality:

- Turn unit on;
- Turn unit off again.

If the unit cannot be turned off using the On/Off button, the unit contains a damaged component. The device should be taken out of service and quarantined until it is replaced by Laerdal under this Recall.

- Actions to be taken to ensure continued safe use of the LCSU4 until you receive a Recall replacement unit

You can continue to use your LCSU4 unit until you receive a Recall replacement unit, but it is recommended to implement the following extra safety measures:

- Store the LCSU4 unit without the full charged battery connected so that it cannot turn on by itself. Disconnect the LCSU4 from External Power.
- Perform routine checks of the On/Off functionality by turning the unit on and off using the On/Off button.

- Actions to be taken if the On/Off functionality fails during clinical use

If the Off functionality fails during clinical use, you can continue to use the Unit. The safety and effectiveness of the device is not affected by the failure of the On/Off button as long as it has power. The unit can be turned off by removing the battery or the external power source.

Transmission of this Urgent Device Recall:

If you have further distributed this product, please provide a copy of this Urgent Device Recall Notice to other organizations on which this action has an impact, i.e. all staff involved in the maintenance, charging and use of the Laerdal Compact Suction Unit 4.

Please maintain awareness of this Urgent Device Recall and the required action for an appropriate period.

Actions to be taken by Laerdal to mitigate the problem

Laerdal Medical will replace all affected standard versions of LCSU4 (88005101 / 88006101) with a new Replacement Unit, (Item Number 881151) which comes with no included accessories (i.e. Battery, External Power Supply, Wire stand, Canister, Carry Case or Suction Tubing).

Laerdal Medical will replace all affected RTCA versions of LCSU4 (88005201 / 88006201) with a new Replacement Unit, (Item Number 881152) which comes with no included accessories (i.e. Battery, External Power Supply, Wire stand, Canister, Carry Case or Suction Tubing).

Customers do not have to order Replacement Units. Laerdal Medical will arrange for affected standard/RTCA LCSU4s to be replaced.