

Urgent Field Safety Notice 2016-R-04

Laerdal Compact Suction Unit® 4 (LCSU® 4) cannot be turned off, or turns on by itself.

Date: 21 November 2016

Important Note! This Urgent Safety Notice only applies to Laerdal Compact Suction Units 4 (LCSU 4) manufactured since 1 May 2015.



LCSU 4 300 ml (3.3 lbs) canister version



LCSU 4 800 ml (4.3 lbs) canister version

Details on affected devices:

All the devices manufactured since May 2015 with item numbers listed below:

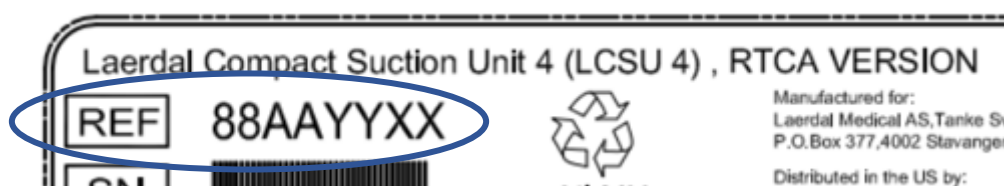
Standard Version:

- 88005101 - LCSU 4, 800 ml Complete unit (US)
- 88005103 - LCSU 4, 800 ml Complete unit (UK)
- 88005140 - LCSU 4, 800 ml Complete unit (EUR)
- 88006101 - LCSU 4, 300 ml Complete unit (US)
- 88006103 - LCSU 4, 300 ml Complete unit (UK)
- 88006140 - LCSU 4, 300 ml Complete unit (EUR)
- 881151 - Replacement unit

RTCA Version:

- 88005201 - LCSU 4, 800 ml, RTCA Complete unit (US)
- 88005203 - LCSU 4, 800 ml, RTCA Complete unit (UK)
- 88005240 - LCSU 4, 800 ml, RTCA Complete unit (EUR)
- 88006201 - LCSU 4, 300 ml, RTCA Complete unit (US)
- 88006203 - LCSU 4, 300 ml, RTCA Complete unit (UK)
- 88006240 - LCSU 4, 300 ml, RTCA Complete unit (EUR)
- 881152 - Replacement Unit, RTCA

The item numbers can be found on the label on bottom of the device, next to the REF symbol, as shown below:



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Description of the problem:

The On/Off functionality in the LCSU 4 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 LCSU 4 cannot be turned off, and it may turn on by itself.

Typical failure modes are outlined below:

- a) The LCSU 4 turns on by itself. The LCSU 4 continue to run until the battery is drained, and the LCSU 4 will not operate. If a new battery is inserted, or if the unit is connected to an external power source, the LCSU 4 starts running by itself again. When it is running, it is not possible to turn the unit off using the On/Off Button.
- b) The LCSU 4 start running by itself while connected to an external power source. The LCSU 4 cannot be turned off using the On/Off Button.
- c) The LCSU 4 can be turned on using the On/Off button. The LCSU 4 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.

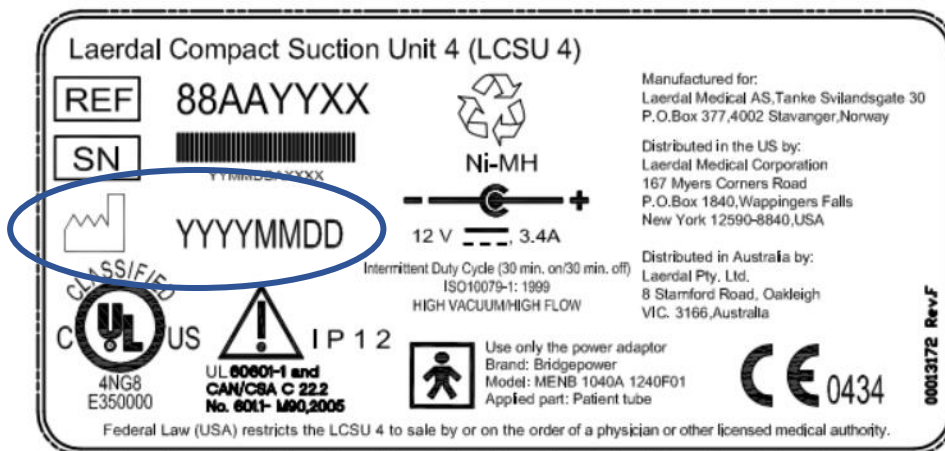
Advise on action to be taken by the user:

- Identify affected Laerdal Compact Suction 4 units:

This Urgent Field Safety Notice covers all LCSU 4 units manufactured from 1 May 2015. The LCSU 4 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:



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Exception: Some LCSU 4 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.



- **Check On/Off functionality:**

You can 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.

The safety and effectiveness of the device is not affected by the failure of the On/Off button as long as it has power.

Note that even if the unit passes this test, the problem may occur later. The actions below must be taken to ensure continued safe use of the LCSU 4 until you receive a replacement unit.

- **Actions to be taken to ensure continued safe use of the LCSU 4 until you receive a replacement unit**

You can continue to use your LCSU 4 unit until you receive a replacement unit, but it is recommended to implement the following extra safety measures:

- Store the LCSU 4 unit without the battery connected so that it cannot turn on by itself.
- Perform routine checks of the On/Off functionality by turning the unit on and off using the On/Off button.

All units with failing On/Off functionality should be removed from service.

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

If the On/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.

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Actions to be taken by Laerdal to mitigate the problem

- **Standard Versions**

Standard versions of LCSU 4 have item numbers starting with 880051 or 880061. This version is not approved for use in aircrafts.

Laerdal Medical will replace all affected standard versions of LCSU 4 with new Replacement Units; pump only, without battery, external power supply, wire stand, canister or tubing (Item Number 881151).

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

- **RTCA Version**

RTCA versions of LCSU 4 have item numbers starting with 880052 or 880062. The label on the bottom of the device specifies that it is an RTCA version.

Laerdal Medical is looking into solutions to correct the problem, and will be back with further information relative to the RTCA version.

Transmission of this Urgent Field Safety Notice:

Please transfer this Urgent Field Safety Notice to other organisations 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 Field Safety Notice and the required action for an appropriate period.

Contact reference person:

Claudia Pajares Ibanez

Regulatory Affairs Specialist
Laerdal Medical AS

Claudia.Pajares.Ibanez@laerdal.com



Dear Customer

21 November 2016

This letter contains important information about your **Laerdal Compact Suction Unit® 4 (LCSU® 4)**. Please read this letter and the attached Urgent Field Safety Notice.

Laerdal Medical has become aware of a problem related to the On/Off functionality of the LCSU 4. You may experience that:

- it is not possible to turn the LCSU 4 unit off, without removing the power source; or
- the LCSU 4 unit turns on by itself when connected to a power source.

Please note that this Urgent Field Safety Notice is only applies to LCSU 4 units **manufactured** after May 2015. Note: If you purchased units in or after May, the units may be unaffected.

**This document contains important information for the continued safe use of
Laerdal Compact Suction Unit – LCSU 4**

Please review the Urgent Field Safety Notice with all personnel involved in the maintenance, charging and use of the Laerdal Compact Suction Unit, LCSU 4. It is important to understand the implications of this communication.

Please retain a copy of the Urgent Field Safety Notice.

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

- How to identify affected units;
- Actions to be taken by you as customer to ensure continued safe use of the Laerdal Compact Suction Unit 4 (LCSU 4) until a replacement device is available;
- Actions to be taken by Laerdal Medical.

If you should have any questions, please contact your local Laerdal Medical Company customer service organization.

This Urgent 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.

Laerdal Medical AS