Urgent Field Safety Notice 2020-R-02

Risk of Laerdal Compact Suction Unit® 4 (LCSU® 4) proving reduced suction levels or failing to provide suction

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Date: 20 October 2020

Important Note! This Urgent Safety Notice only applies to Laerdal Compact Suction Units 4 (LCSU 4) manufactured in the period 9 August 2018 to 6 June 2020.

LCSU 4 300 ml (3.3 lbs) canister version

LCSU 4 800 ml (4.3 lbs) canister version

Description of the problem:

The service life of LCSU 4 units manufactured in the period 9 August 2018 to 6 June 2020 may be reduced due to weakness in the design and assembly process. The pump of the affected units may malfunction resulting in low suction levels or failure to provide suction.

What Laerdal Medical will do to address the problem:

Laerdal Medical will replace affected devices with new LCSU 4 Replacement Units, free of charge (catalogue numbers 881151 and 881152).

Actions to be taken by LCSU 4 users:

1. Identify affected Laerdal Compact Suction 4 units:

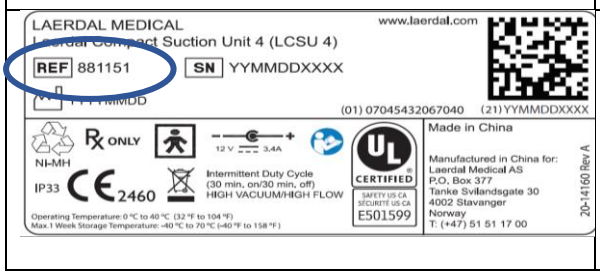
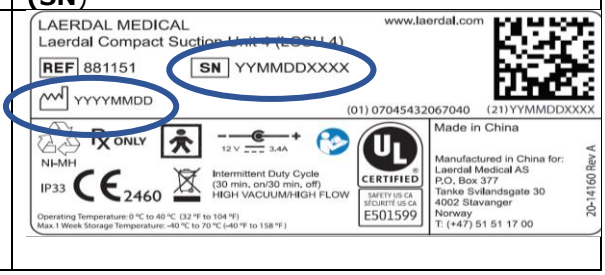
This Urgent Field Safety Notice covers LCSU 4 units with Catalogue Numbers listed below:

- 880051 - LCSU 4, 800 ml Complete unit
- 880061 - LCSU 4, 300 ml Complete unit
- 881151 - Replacement unit
- 880052 - LCSU 4, 800 ml, RTCA Complete unit
- 880062 - LCSU 4, 300 ml, RTCA Complete unit
- 881152 - Replacement Unit, RTCA

Units affected by this Urgent Field Safety Notice are labelled with:

- Manufacturing Dates (format YYYYMMDD) in the range 20180809 to 20200606; and
- Serial Numbers in the range 1808090003 to 2006060045

The Catalogue Number, Manufacturing Date and Serial Number can be found on the label on bottom of the LCSU 4 unit:

Catalogue Number	**Manufacturing Date** and **Serial Number (SN)**
	

2. Secure 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 make note of the following safety measures:

- Follow local protocols for back-up suction devices. Do not repeatedly block the patient tube for more than 10 seconds at a time at vacuum levels greater than 300 mmHg.
- Only use canisters, tubes and accessories that are approved for the device by Laerdal Medical.
- When adjusting the vacuum level: When the desired vacuum level is reached; unblock the patient tube immediately.
- During patient treatment do not occlude or block the patient tube by intentional bending or squeezing. The patient tube should only be temporarily occluded by suctioning matter.
- When performing the Device Test: When the vacuum reaches minimum 500 mmHg immediately release the blocking.

Replacement units

Laerdal will ship replacement units, free of charge. Customers do not have to place orders for Replacement Units; Laerdal Medical will arrange for all affected units to be replaced.

Note that the Replacement Units are shipped without carry bag, battery, external power supply, wire stand, canister or tubing.

When you receive the replacement unit, you will be instructed to dispose of the pump unit, but to keep the carry bag, battery, external power supply and wire stand of your existing unit. You will be asked to confirm disposal of the replaced unit in writing by completing the Customer Feedback Form.

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 reprocessing, 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:

Vania Alexieva

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Laerdal Medical AS

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