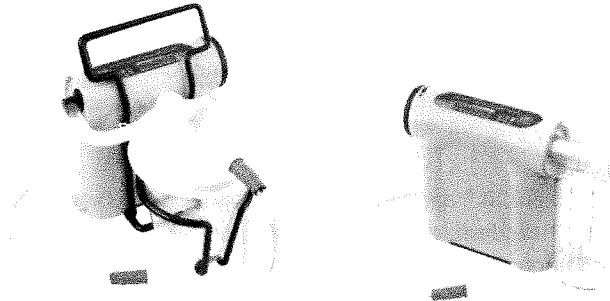


Laerdal Medical
MEDICAL DEVICE RECALL
NOTIFICATION FOR USERS
LAERDAL COMPACT SUCTION UNIT® LCSU 4 RTCA

Date: 01/15/2026

Purpose of this Notice

Laerdal Medical AS is conducting a voluntary recall for certain LCSU 4 RTCA devices manufactured between March 28, 2024, and May 12, 2025. The Laerdal Compact Suction Unit 4 (LCSU 4) is a portable, electrically powered suction device intended for field and transport use.



This communication is issued to:

- Describe the identified issue.
- Provide accurate information to ensure transparency in product labeling and continued use.
- Explain how to identify affected units.
- Request acknowledgment that you have received and understood this notice.

As part of Laerdal's customer-care commitment, customers are also provided with instructions for how to receive an RTCA-compliant replacement unit at no cost (Catalogue 881152).

Reason for Voluntary Recall:

It has come to the attention of Laerdal that LCSU 4 RTCA units manufactured in a limited time period may emit electromagnetic noise beyond the acceptable limits for RTCA application specified in RTCA DO-160G Chapter 21, Equipment Category M. It is important to note that the electromagnetic emissions are significantly below the limit in the standard for electro medical devices (IEC 60601-1-2). Compliance with RTCA/DO-160G Section 21 Category M (for battery operation only; commercial aircraft, airborne equipment) is stated in the User Guide (UG) and in the model designation "LCSU 4 RTCA" on the product label.

Note: Laerdal has not received any customer complaints or reports of injuries caused by the issues described in this letter.

Risk Assessment:

Laerdal's Health Hazard Evaluation determined that affected units are unlikely to cause any adverse health outcomes. The core functionality of the LCSU 4—to remove secretions, blood, or vomit from a patient's airway to facilitate ventilation—remains unaffected.

RTCA DO-160G is an aviation-specific electromagnetic emissions standard intended to protect aircraft avionics from interference, not a requirement for demonstrating the medical safety or effectiveness of suction equipment. The likelihood of interference is low as there is a substantial gap between the emission limits and the susceptibility limits.

Labeling Correction:

This notice serves as the required user guide and labeling addendum for affected devices.

Original UG statements:

“Cat. No. 880052/880062 are approved according to RTCA/DO-160G Section 21 Category M but limited to battery operation use only.”

“Certifications Cat. No. 880052/880062: Meets RTCA/DO-160G – Section 21 Category M (for battery operation only; commercial aircraft, airborne equipment).”

Corrected statement:

The units affected in this notice do not meet RTCA DO-160G Section 21 Category M requirements. Although catalogue number 881152 is not explicitly referenced in the existing UG, it shares the same design and labeling and is therefore included within the scope of this correction.

The model identifier “LCSU 4 RTCA,” appearing on the product label (seen at bottom of model), also implies conformance to this standard; affected units do not conform to RTCA DO-160G Section 21 Category M. Please see representative example:



This correction applies only to the units identified in this notice.

How to Identify Affected Devices:

Laerdal Compact Suction Unit 4 – RTCA version (LCSU 4 – RTCA):

Device Name	Catalogue number	UDI-DI (GTIN)
LCSU 4, 800 ml, RTCA	880052	07045432088519
LCSU 4, 300 ml, RTCA	880062	07045432088533
LCSU 4, RTCA	881152	07045432067132

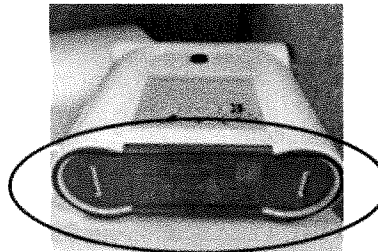
Units affected by this Medical Device Recall Notice are labelled with:

- Laerdal Compact Suction Unit (LCSU 4) RTCA (RTCA identification can be found both on the label indicated below and molded with the word "AIRCRAFT" into the back of the device) Catalogue numbers: 880052, 880062, 881152
- Manufacturing Dates (format YYYY-MM-DD) from 2024-03-28 to 2025-05-12
- Serial Numbers (SN): 88WWYXXXXX in the range 88012565572 to 88522465342

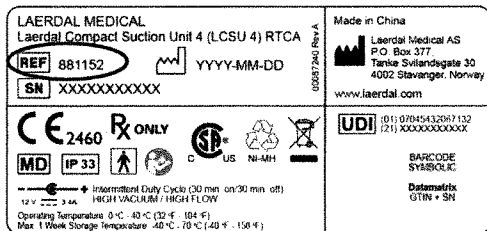
Units excluded from affected serial range:

88142460168	8814260169	88142640176	8814260177
8814260181	88142460183	88142460184	88142460185
88142460186	88142460187	88142460188	88142460189
88142460190	88142460191	88142460192	88142460193
88142460194	88142460195	88142460196	88142460198
88142460204	88142460205	88142460206	88142460207
88142460208	88142460210	88142460212	88142460214
88142460215	88142460220	88142460221	88142460277
88142460228	88142460280	88142460281	88142460282
88142460283			

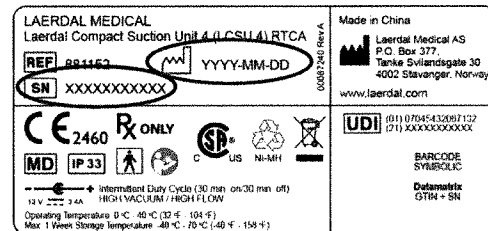
The device name, catalogue number, manufacturing date, and serial number can be found on the label on the bottom of the LCSU 4 RTCA unit. See illustration below:



Catalogue Number (REF)



Manufacturing Date and Serial Number (SN)



Mandatory Actions to be Taken:

1. Please review this notice carefully and provide acknowledgment that you have received and understood the contents by completing *Acknowledgement and Replacement Form*.
2. Ensure that this notice is shared with all relevant personnel involved in the storage, maintenance, charging, and use of the LCSU 4 RTCA device.
3. Maintain this information for your records.

Optional Laerdal Customer Care Initiative Replacement Request:

As part of Laerdal's commitment to customer service, RTCA/DO-160G Section 21 Category M compliant replacement units are being offered, free of charge. To receive a replacement, you must reply within 2 weeks of receipt, with the following information:

1. Confirm acknowledgment of this notice as mentioned above.
2. Confirm serial numbers of your affected units and shipping address in your reply.

Once validated, Laerdal Medical will arrange for your affected unit(s) to be replaced at no cost.

Important: Replacement units (881152) are shipped **without** a carry bag, battery, external power supply, wire stand, canister, or tubing. Please retain these accessories from your existing unit for continued use.

Customers are required to confirm responsibility for disposing of the replaced LCSU 4 RTCA Unit(s) in accordance with applicable environmental regulations. Proof of disposal must be retained and made available upon request. By accepting the replacement, the customer releases Laerdal from any future claims or liabilities related to the old unit.

Note that when requesting a replacement unit, the warranty coverage that will apply is that of the original unit. The replacement does not alter the conditions or extend the validity of the initial warranty granted for the original LCSU 4 RTCA unit.

Please maintain awareness of this notice and the related actions for your records.

Contact Information:

LCSU4 Recall Support

Email: LCSU4recall@laerdal.com

Phone: 877-846-3963

Monday through Friday 8:30 to 4:30 PM

Please reference LCSU 4 RTCA Recall and your Case Number in all correspondences

Adverse reactions or quality problems experienced with the use of this product may be reported to the appropriate regulatory authority in the jurisdiction where the device is used:

United States: FDA MedWatch Adverse Event Reporting program (online, regular mail, or fax).

Canada: Health Canada's Medical Device Problem Reporting Program (online portal, email, or mail).

Authorized by:

Gwynneth Thomas

Director, Therapy Products

Laerdal Medical

Laerdal Medical
MEDICAL DEVICE RECALL
ACKNOWLEDGEMENT AND REPLACEMENT FORM
LAERDAL COMPACT SUCTION UNIT® LCSU 4 RTCA

- I acknowledge and understand the Medical Device Recall Communication for Users.
- I confirm responsibility for disposing of the replaced LCSU 4 RTCA Unit(s) in accordance with applicable environmental regulations. Proof of disposal must be retained and made available upon request. By accepting the replacement, I release Laerdal from any future claims or liabilities related to the old unit.

Important: Replacement units (881152) are shipped **without** a carry bag, battery, external power supply, wire stand, canister, or tubing. Please retain these accessories from your existing unit for continued use. When requesting a replacement unit, the warranty coverage that will apply is that of the original unit. The replacement does not alter the conditions or extend the validity of the initial warranty granted for the original LCSU 4 RTCA unit.

REPLACEMENT REQUEST INSTRUCTIONS

Complete one form per ship-to address. If replacement units are needed at multiple addresses, submit another form for each ship-to address.

List all affected serial numbers located at the address below. Once validated, Laerdal will ship replacement units equal to the number of listed serial numbers.

SHIP-TO INFORMATION:

Name of Organization:

Phone Number of Organization:

Contact Name:

Shipping Street:

Shipping State:

Contact Email Address:

Shipping City:

Shipping Zip Code:

Affected Serial Number(s) at this address:

PLEASE SEND COMPLETED FORM(S) TO:

Email: LCSU4recall@laerdal.com