

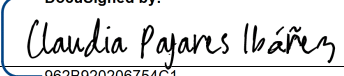
# LAERDAL FIELD CORRECTIVE ACTION ALERT

## 2025-R-04: LCSU 4 RTCA Replacement

<b>To:</b>	
<b>Market</b>	<b>Local Field Corrective Action Coordinators</b>
Australia	Haritha Kunnummal
Austria	Stefanie Hamberger
Canada	Gina Beshai
Denmark	Sigve Oaland
Finland	Annika Häkkinen
France	Sebastien Vivier
Germany	Stefanie Hamberger
Italy	Novella Callero
Korea	Judy Lee
Malaysia	Kenneth Ng, Mohd Ihwanuddin
Netherlands	Robin Van Craenenbroeck
New Zealand	Haritha Kunnummal
Norway	Sigve Oaland
Singapore	Kenneth Ng, Mohd Ihwanuddin
Spain	Joseph Belandria
Sweden	Markus Centervall, Annika Häkkinen
Switzerland	Stefanie Hamberger
United Kingdom	Carol-Anne Haffie
USA	Gina Beshai
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Field Corrective Action Initiation Date	18 November 2025

Summary of Field Corrective Action	Laerdal will replace affected LCSU 4 RTCA devices with new replacement units, free of charge. Customers will need to confirm that they would like a replacement unit and that they will dispose of their old one(s), after receiving their replacement unit.
Documentation Package included with the Field Corrective Action Alert	<ul style="list-style-type: none"><li>• FCA Strategy</li><li>• Field Notice</li><li>• Customer Letter</li><li>• Unit Affected List (UAL)</li></ul>

Best Regards,

DocuSigned by:  
  
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Claudia Pajares Ibanez

Corporate Field Corrective Action Coordinator

## Laerdal Internal Field Corrective Action Information

<i>Laerdal Field Corrective Action Identification Number</i>	<b>2025-R-04</b>
<i>Description of Field Corrective Action</i>	<p>As part of the design verification activities for an upcoming regulatory submission for LCSU 4, EMC testing was performed on the RTCA configuration of the LCSU 4 to verify compliance with RTCA DO-160G Section 21, Equipment category M. It was discovered that the LCSU 4 RTCA version had been manufactured using a wrong component on 20-13657 (PCA Motor EMI Filter) between 28<sup>th</sup> March 2024 and 12<sup>th</sup> May 2025.</p> <p>When requested by the customer, Laerdal will replace affected units. Customers do not have to order replacement units; Laerdal will ship new Replacement Units (Cat No 81152) to Laerdal customers/distributors who have purchased affected LCSU 4 RTCA units.</p> <p>For units sold via distributors, the individual Laerdal sales teams must work with the distributors to arrange for shipment of units.</p>
<i>Affected Products</i>	<ul style="list-style-type: none"> <li>• LCSU4, 800 ml, RTCA – 880052</li> <li>• LCSU4, 300 ml, RTCA – 880062</li> <li>• LCSU4, RTCA – 881152</li> <li>• LCSU4, 800ml, RTCA(KOR) – 88005227</li> <li>• LCSU4, 300ml, RTCA(KOR) – 88006227</li> </ul>
<i>Affected Serial Numbers</i>	<p>Affected units by this FCA are labelled with Serial Numbers in the range 88132406135 to 88202568266, and with manufacturing dates in the range 28 March 2024 to 12 May 2025.</p> <p>Note: 38 units within this range were manufactured with the correct component and have been excluded from the unit affected list. See FCA Strategy and Field Notice for detailed serial numbers.</p>
<i>Reason for Field Corrective Action</i>	<p>The background and reason for the Field Corrective Action is described in detail in the 2025-R-04 FCA Strategy.</p>

<i>Risk/Hazard situation</i>	<p>With the changed component, LCSU 4 RTCA exceeded the emission limits specified in the RTCA DO-160G standard and may result in the device emitting beyond the acceptable limits for RTCA application. However, the likelihood of interference is low as there is a substantial gap between the emission limits and the susceptibility limits.</p> <p>The core functionality of the LCSU 4 (intermittent operation to remove secretions, blood or vomit from a patient's airway to allow ventilation) is unaffected by the PCA Motor EMI Filter.</p>
<i>Disposition of affected products</i> i. <i>Used, in field</i>	<p>i. Affected units in field to be replaced with new replacement units</p>
<i>Availability schedule for replacement units</i>	<p>Replacement units will start to be manufactured by the end of October 2025 and at a rate of approximately 350 units per week over the next four to five weeks.</p>
<i>Documentation of FCA and resources</i>	<p>Activities towards customers should be recorded in Salesforce.</p> <p>Communication with authorities must be uploaded to the Teams site in the country specific folder.</p> <p>Hours must be registered in MinWinTid, or Excel tracking sheet in Teams site.</p> <p>Use Project Code PG002508 to register hours and costs.</p>
<i>Other information</i>	<p>Unit Affected List (UAL) enclosed as excel format.</p>