Resmed

URGENT FIELD SAFETY NOTICE

Astral 100/150 – Ventilator may stop delivering therapy due to internal component issue

Date:	25 June 2026
Reference:	Astral-2026-FSN-01
SRN:	AU-MF-000011753
Affected Product:	Astral 100 and Astral 150 ventilators and PCBA Spares built prior to October 20. See **Appendix B** for serial number information.

Indications for use

The Astral 100/150 provides continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital, and portable applications for both invasive and non-invasive ventilation.

Description of issue

Resmed is bringing to your attention an issue affecting a subset of Astral 100 and Astral 150 ventilators ("Ventilator").

An internal electrical component (supercapacitor) may leak electrolyte over time. In rare cases, this may damage specific circuitry on the Ventilator's printed circuit board assembly ("PCBA"), causing the ventilator to inadvertently enter a fail-safe state.

If the issue occurs while the Ventilator is delivering therapy:

- **Therapy stops**.
- A high-priority audible alarm (maximum volume alarm) activates.
- The user interface may display therapy alarms and a Safety System Fault red screen.
- When the "Vent Stop" button is pushed, the user interface displays System Fault 140.

If the issue occurs while the Ventilator is in standby:

- A maximum volume alarm activates. A user interface message may not be displayed.
- If therapy is initiated, **therapy will not start**.

In both cases the Ventilator is no longer able to deliver therapy. Alternative means of ventilation must be provided.

Potential risk to patients

A hazardous situation may arise if **all** the following occur:

- The supercapacitor has leaked; AND
- The leak damages specific PCBA circuitry; AND
- The damage causes the Ventilator to inadvertently enter a fail-safe state.

Patients who are unable to maintain adequate spontaneous ventilation may be at risk of serious injury or death if therapy is interrupted and alternative means of ventilation is not promptly initiated.

Based on Resmed's investigation and analysis of global post-market and service data, the occurrence rate of specific circuitry damage causing the ventilator to inadvertently enter a fail-safe state is 0.1%. Resmed has received 5 reports of adverse events, of which 1 was classified as serious. All patients recovered following intervention.

Patients should not discontinue therapy unless an appropriate alternative means of ventilation is available and they are instructed to do so by their treating clinician.

Important Care and Monitoring Information

Resmed would like to reinforce the importance of following the Astral 100/150 User Guides and Clinical Guides, including recommendations relating to monitoring, emergency preparedness, caregiver training, and availability of backup ventilation equipment whenever the ventilator is being used.

These guides include the following important instructions:

- *For ventilator-dependent patients, always have alternate ventilation equipment available, such as a back-up ventilator, manual resuscitator or similar device. Failure to do so may result in patient injury or death.*
- *Ventilator-dependent patients should be continuously monitored by qualified personnel or adequately trained carers. These personnel and carers must be capable of taking the necessary corrective action in the event of a ventilator alarm or malfunction.*

It is important to ensure that carers are appropriately trained, that this training is up to date, and that they are confident in responding to alarms and emergency situations.

Ensure that alternative ventilation equipment is not only available but is functional, regularly checked, and ready for immediate use if required.

Products Affected

The affected population includes:

- Astral 100 ventilators built prior to October 2024
- Astral 150 ventilators built prior to October 2024
- Astral 100 PCBA spare parts built prior to October 2024
- Astral 150 PCBA spare parts built prior to October 2024

Each customer will receive a list (based on Resmed's records) of impacted ventilators and PCBA spare parts, including serial number and Unique Device Identifier (UDI), where applicable.

Refer to **Appendix B** for instructions on identifying Astral ventilator and PCBA serial numbers.

Note, this list includes only ventilators and PCBA spare parts supplied directly by Resmed and may not represent the full population of affected ventilators within your managed fleet.

If the PCBA in a ventilator has previously been replaced, the replacement PCBA should be verified to determine whether it is affected by this issue. Ventilators fitted with a non-affected replacement PCBA are not impacted by this issue. Please inform Resmed of these ventilators through the affected ventilator status process described below.

Device service life consideration

As set out in the User Guide, the Astral ventilator has an expected service life of 8 years when maintained in accordance with Resmed instructions.

For devices beyond the 8-year service life, consider transitioning patients to alternative ventilator options where appropriate.

Affected Ventilator Status

To support regulatory traceability requirements, healthcare providers and distributors are required to report the status of affected ventilators to Resmed.

This includes:

- Ventilators no longer in use.
- Ventilators already corrected with unaffected PCBAs.
- Ventilators no longer managed by your organisation.

To assist in the return of this information to Resmed, a template can be downloaded from www.resmed.com/astralfsn-status to fill in and return to astralresponse@resmed.com.

Important information regarding device correction and component availability

At this time, the availability of PCBAs is significantly constrained, and it is not possible to immediately correct all affected ventilators.

As a result, Resmed is implementing a prioritised and phased approach initially focused on inspection and risk mitigation activities for patients at highest clinical risk.

Resmed is continuing to evaluate potential additional corrective action pathways for the affected population. Further communication and updated instructions regarding any additional actions that may be required will be provided as they become available.

These supply constraints are also expected to affect the availability of new Astral ventilators. Accordingly, alternative ventilator options should be prioritised for new patients, noting that availability may vary by product and country.

Actions by Resmed

Resmed is implementing a phased Field Safety Corrective Action (FSCA) to address this issue.

During Phase 1, patients considered to be at greatest risk of harm in the event of an unexpected interruption to ventilation will be prioritised. To support implementation of this approach, **Appendix A** provides a patient prioritisation framework and the corresponding Phase 1 actions for each risk category. This framework is intended to support allocation of available correction resources according to patient clinical risk, while recognising current constraints on PCBA availability.

Resmed will:

- support clinicians in identifying higher-risk patients through the framework set out in **Appendix A**. This tiered framework is provided for guidance only and does not replace clinical judgement. Clinicians should apply their clinical judgement to identify patients who may be at greatest risk of harm in the event of an unexpected interruption to ventilation.
- issue and maintain Technical Service instructions (including Tech Note 1063720) defining current inspection, servicing and PCBA replacement processes.
- support inspection and correction activities for affected ventilators that meet the criteria outlined in this letter.
- continue to monitor post-market data and evaluate additional corrective action pathways, including monitoring component supply availability.
- provide further communications and updated instructions to customers regarding any additional actions that may be required, as they become available.

Actions to be taken by healthcare providers and distributors

Due to limited availability of PCBAs, immediate correction of all affected ventilators is not possible. Healthcare providers are required to implement risk mitigation measures and support prioritisation of devices for inspection and limited initial correction activities in accordance with Resmed guidance.

Healthcare providers and distributors are required to:

- Complete and return the acknowledgment form by July 31, 2026.
- Immediately provide a copy of this notice, together with the physician letter and patient/carer communication, to all relevant healthcare professionals, patients, and carers.
- Reinforce adherence to the Astral User Guide and Clinical Guide instructions, including ensuring that ventilator-dependent patients are appropriately monitored, that carers are trained and confident in responding to ventilator alarms and emergency situations, and that appropriate alternative ventilation equipment is functional, regularly checked, and immediately available where required.
- Avoid removing affected ventilators from use unless an appropriate alternative means of ventilation is immediately available. Patients should continue therapy unless otherwise directed by their treating clinician.
- Review affected patients and assess their clinical risk category (Tier 1, Tier 2 or Tier 3) using **Appendix A** and clinical judgement.
- Arrange inspection of affected ventilators in accordance with the Phase 1 Inspection and Correction Strategy in **Appendix A.** Return ventilators to an authorised service centre when required.
- Continue to follow Resmed service and maintenance processes, including the 2-year preventative maintenance schedules and current Technical Service instructions (including Tech Note 1063720 and subsequent updates).
- Identify affected ventilators within your control and review the serial number list provided by Resmed. Using the response mechanism outlined in the **Affected Ventilator Status** section of this letter, provide the current status of affected ventilators, including whether the ventilator has previously undergone corrective main PCBA replacement, or has been scrapped or removed from use.
- Monitor future communications from Resmed. Resmed will provide further communications and updated instructions regarding additional actions that may be required as they become available.
- For new patients, prioritize alternative ventilator options due to the significantly constrained availability of Astral ventilators.

Actions for service centres

- Identify any PCBA Spares that are in your possession with a serial number below 22241978070 and return them to Resmed.

- Perform servicing, corrective actions and data collection in accordance with the latest Technical Service instructions, including Tech Note 1063720. As Technical Service instructions are updated, progressively expand replacement activities in line with updated guidance.

Manufacturer

ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista 2153
Australia

We appreciate your support in this matter and consider this action necessary to ensure that our customers and patients receive products of the highest quality. Resmed apologises for any inconvenience that this requested action could create.

Resmed has previously informed Competent (Regulatory) Authorities about this communication where affected Ventilators have been distributed, in accordance with local regulations.

For any questions, please contact your local Resmed contact.

Sincerely,

Resmed Quality Assurance and Regulatory Affairs

CUSTOMER ACKNOWLEDGEMENT FORM

Reply form to Field Safety Notice – Astral 100/150 – Ventilator May Stop Delivering Therapy Due to Internal Component Issue

To ensure compliance with regulatory action traceability requirements, please complete this form in full and send it back by e-mail by July 31, 2026, to astralresponse@resmed.com.

I confirm receipt of this Field Safety Notice, and I confirm that I have read and understood its content.

I have forwarded this information as appropriate.

Name of Healthcare Provider / Distributor / Customer	
Address of Healthcare Provider / Distributor / Customer	

Name	
Position	
Email address / Phone number	
Signature	
Date	

You received this notice as a registered contact relating to the purchase of Resmed Astral ventilators subject to a field safety notice. Your information, as well as the data entered in the above form, is exclusively processed in the context of our regulatory reporting obligations. The data will be securely stored by Resmed and retained only for the purpose of complying with our regulatory requirements, and at most for 15 years after the last applicable sale. This data may be accessed by trained Resmed regulatory and quality team members outside of your region in conformity with our privacy notice available at me.Resmed.com/privacynotice. For any further information regarding the processing of personal data, please contact us at privacy@Resmed.com.

Appendix A

Patient prioritisation should be determined by a clinician who is able to assess individual patients based on their current ventilatory support needs. It is recognised that a patient's clinical status and ventilatory requirements may change over time.

This tiered framework is provided for guidance only and does not replace clinical judgement. Clinicians should apply their clinical judgement to prioritise those patients who are at greatest risk of severe harm in the event of an unexpected interruption to ventilation.

Clinical risk categorisation

Tier	Risk of harm	If therapy is interrupted, the patient may experience	May include patients who meet one or more of the following criteria (non-exhaustive)	Phase 1 Inspection and Correction Strategy
1	Highest potential risk of harm	Rapid desaturation, immediate respiratory distress, high likelihood of serious harm if therapy is not promptly restored	• Have no or limited ability to maintain spontaneous ventilation (e.g. unable to tolerate interruption of therapy for ≥5 minutes) • Require continuous or near-continuous ventilation (e.g. >20 hours/day) • Have invasive ventilation (e.g. tracheostomy) • Have rapidly progressive neuromuscular disease (NMD) – especially for paediatric patients.	• If the next preventative maintenance service is due within the next 12 months, inspect the ventilator at the next scheduled preventative maintenance service. • If the next preventative maintenance service is due more than 12 months from now, arrange an inspection of the ventilator within the next 12 months. • If inspection identifies evidence of supercapacitor leakage, replace the affected PCBA in accordance with current Technical Service instructions.
2	Moderate potential risk of harm	Desaturation and gradual respiratory distress	• Cannot maintain spontaneous ventilation ≥ 4 consecutive hours • Require ventilation ≥10–20 hours/day • Have limited spontaneous reserve, likely to deteriorate	• Inspect the ventilator at the next scheduled preventative maintenance service. • If inspection identifies evidence of supercapacitor leakage, replace the affected PCBA in accordance with current Technical Service instructions.

Tier	Risk of harm	If therapy is interrupted, the patient may experience	May include patients who meet one or more of the following criteria (non-exhaustive)	Phase 1 Inspection and Correction Strategy
			gradually without ventilator support	
3	Lower potential risk of harm	Non-life-threatening symptoms or return to baseline condition	• Use ventilation intermittently or for symptom management • Have stable COPD or chronic respiratory failure • Can maintain adequate spontaneous ventilation for extended periods without support throughout the day/night • Likely return to baseline if therapy is interrupted	• Continue use of the ventilator in accordance with this letter and current service recommendations. • Inspection and any additional corrective actions will be addressed in future phases of the FSCA.

Patient prioritisation should not be based on individual criteria in isolation. Overall patient risk should be assessed holistically, taking into account both clinical dependency and the broader context in which the device is used.

The presence of robust and reliable mitigating measures may reduce overall patient risk. Conversely, the absence of such measures, or the presence of additional risk factors, may increase overall risk and influence prioritisation.

Additional factors that may increase overall risk include:

- Particularly vulnerable patient populations (e.g. paediatric patients).
- Remote or regional settings where emergency response may be delayed.
- The age of the device, as component ageing may contribute to an increased likelihood of supercapacitor leakage over time

Additional factors that may reduce overall risk include:

- Hospital setting or proximity of emergency care.

These factors should be considered together to support clinical judgement in determining overall patient risk and appropriate prioritisation.

Appendix B

Affected Astral 100 and Astral 150 ventilators and Astral PCBA Spares that were built prior to October 2024.

If a ventilator has had the PCBA replaced, review the PCBA serial number to determine if it is still part of the affected population. If it is no longer part of the affected population, inform Resmed via the tool in **Affected Ventilator Status.**

Summary of affected product breakpoints

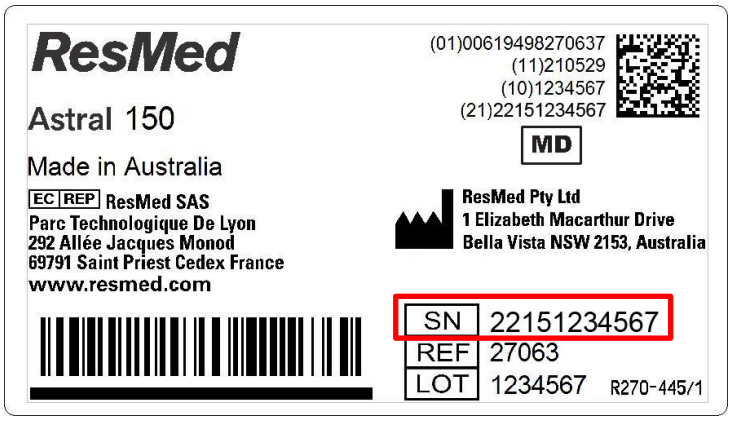
Product Type	Serial Number Location	Affected Criteria
Astral ventilator	Device label	Serial number < 22241890149
Astral PCBA spare part	Physical PCBA or Ventilator user interface	Characters 2–8 < 2707658
Astral PCBA spare part	Box label	Box serial number < 22241978070

Astral ventilators

To determine whether an Astral ventilator is affected:

1. Locate the product serial number on the device label on the bottom of the Astral ventilator.
2. Products with serial numbers **less than 22241890149** are considered affected.

   Example:
   In the image below, the serial number is 22151234567.



Astral PCBA spare part

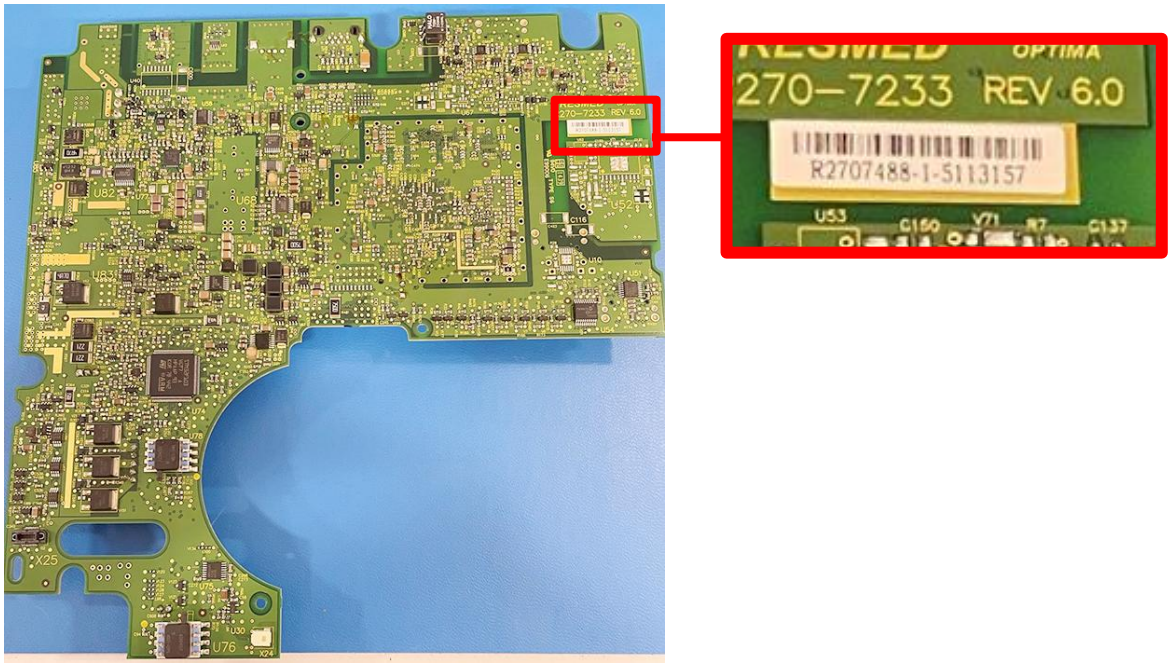
Astral PCBA spare parts contain two serial numbers:

- The serial number on the physical PCBA
- The serial number listed on the box of the spare part

Physical PCBA Serial Number

1. Locate the serial number printed directly on the physical PCBA or via the ventilator user interface.
2. Extract characters **2 through 8** from the serial number.
3. PCBAs where the extracted value is **less than 2707658** are considered affected.

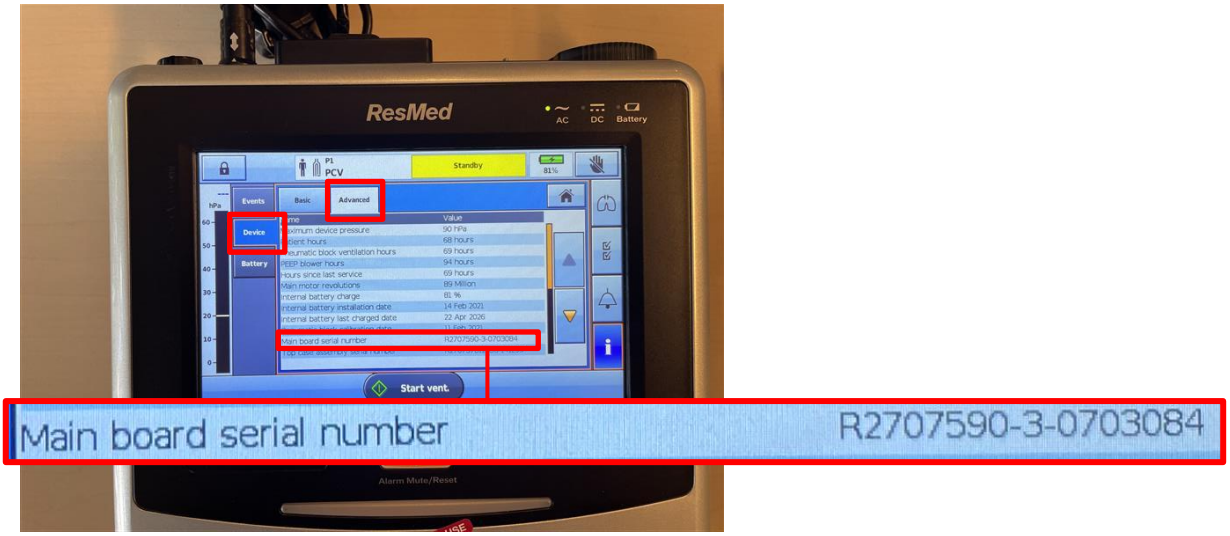
Physical PCBA Example
In the image below, the serial number is R2707590-3-0724827. Characters 2-8 are 2707488.



Example – Physical PCBA Serial Number via User Interface

1. From the home screen, click the button for the Information menu ‘ ℹ ’

2. Navigate to ‘Device’, ‘Advanced’ to view the Main board serial number. In the image below, the serial number is R2707590-3-0703084. Digits 2-8 are 2707590.



Box Serial Number

1. Locate the serial number printed on the spare part box label.
2. Spare parts with box serial numbers **less than 22241978070** are considered affected.

Example

In the image below, the serial number is 22232610058.