Resmed

PHYSICIAN LETTER

Astral 100/150 – Urgent Field Safety Notice – Ventilator may stop delivering therapy due to internal component issue

Date:	25 June 2026
Reference:	Astral-2026-FSN-01
Affected Product:	Astral 100 and Astral 150 ventilators and PCBA spares manufactured prior to October 2024. See **Products Affected** for serial number information.

Dear Clinician,

Resmed is writing to inform you of an issue affecting a subset of Astral 100 and Astral 150 ventilators and to provide guidance for managing patients who may be using affected ventilators.

General Product Description

The Astral 100/150 ventilators provide continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The ventilators are intended for use in home, institutional/hospital, and portable settings for both invasive and non-invasive ventilation.

Description of Issue

Resmed has identified that an internal electrical component (supercapacitor) in a subset of Astral 100 and Astral 150 ventilators may leak electrolyte over time.

In rare cases, the leakage may damage specific circuitry on the printed circuit board assembly (PCBA). This can result in the ventilator inadvertently entering 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.

Clinical Risk

A serious clinical risk 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 spontaneous ventilation, or who do not have access to adequate monitoring or alternative ventilation, may be at risk of serious injury or death if the hazardous situation occurs and therapy is not restored.

Based on Resmed's investigation and analysis of global post-market and service data, the occurrence rate of leak damaging specific circuitry, leading to an inadvertent fail-safe state is 0.1%. Resmed has received 5 reports of adverse events related to this issue, 1 of which was serious. All patients recovered following intervention.

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

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.

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

Important information regarding inspection activities 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 during routine service interactions 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 defining current inspection, servicing, and 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 for Clinicians

Clinicians managing patients using affected Astral ventilators should:

- Review patients using affected ventilators and apply clinical judgement to assess individual patient risk in the event of an unexpected interruption to ventilation. Patients should continue therapy unless an appropriate alternative means of ventilation is available and discontinuation is directed by the treating clinician.
- Support implementation of the Phase 1 inspection and correction strategy described in **Appendix A**, including identifying patients who may be at greatest risk of harm and facilitating inspection activities where appropriate.
- Reinforce adherence to the Astral User Guide and Clinical Guide instructions, including ensuring that ventilator-dependent patients are appropriately monitored, that patients and 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.

Reporting an Adverse Event

If your patient has experienced an adverse event related to the use of an Astral ventilator, please visit www.resmed.com/contact or contact the national Regulatory (competent) Authority.

Manufacturer

ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista 2153
Australia

We appreciate your support in managing this issue and ensuring appropriate care for affected patients.

Sincerely,

Resmed Quality Assurance and Regulatory Affairs

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 consider the overall clinical context and not rely on individual criteria alone. 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.

Additional factors that may reduce overall risk include:

- Hospital setting or proximity of emergency care

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

APPENDIX B

Affected Astral 100 and Astral 150 ventilators and Astral PCBA Spares 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.

Summary of affected product breakpoints

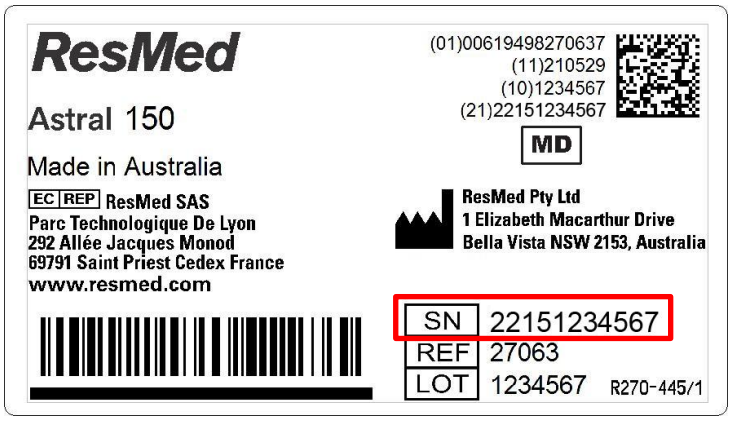
Product Type	Serial Number Location	Affected Criteria
Astral ventilator	Device label	Serial number < 22241890149
Astral PCBA spare part	Ventilator user interface	Characters 2–8 < 2707658

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

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.