

PATIENT / CARER LETTER**Astral 100/150 - Urgent Field Safety Notice - Ventilator may stop delivering therapy due to internal component issue**

Date:	DD MONTH 2026
Reference:	Astral-2026-FSN-01
Affected Product:	Astral 100 and Astral 150 ventilators built prior to October 2024. See Affected Ventilators section for serial number information.

Dear Patient/Carer,

You are receiving this letter because you or someone you care for may be using an Astral 100 or Astral 150 ventilator affected by the issue described below. We would like to provide you with important information about your ventilator. It is important that you read and understand the information contained in this letter.

What is the issue?

In a subset of Astral 100 and Astral 150 ventilators, Resmed has identified that a component, called a supercapacitor, may leak over time. In rare cases, leakage from this component may damage internal parts of the ventilator, causing the device to incorrectly enter a protective safety state.

If the issue occurs while the ventilator is delivering therapy:

- Therapy stops.
- A high-priority audible alarm (maximum volume alarm) activates.
- The ventilator screen may display Therapy alarms and a Safety System Fault red screen.
- When the “Vent Stop” button is pressed, the ventilator screen displays System Fault 140.

If the issue occurs while the ventilator is in standby:

- A high-priority audible alarm (maximum volume alarm) activates. The ventilator screen may not display a message.
- If therapy is started, therapy will not start.

In both cases, the ventilator will no longer be able to deliver therapy. Alternative ventilation support must be started immediately.

Affected Ventilators

Astral 100 and Astral 150 ventilators built before October 2024 with serial numbers below 22241890149.

If the main board in your ventilator has previously been replaced, the replacement main board number should be checked to determine whether it is affected by this issue. Ventilators fitted with a replacement main board that is not affected by this issue are not impacted.

Refer to **Appendix A** for information on how to identify the serial number of your Astral ventilator and main board.

Your healthcare provider or service provider will contact you if your ventilator requires inspection, servicing, or corrective action.

Patient Risk

If this issue occurs during therapy, ventilation may stop unexpectedly. If the ventilator is in standby, it may prevent ventilation from being started.

For ventilator-dependent patients*, there is a risk of harm until alternate means of ventilation is provided.

Should the issue occur, a high priority alarm will sound at maximum volume if therapy is interrupted. The alarm is designed to alert the carer so that immediate action can be taken, including providing alternative ventilation if required.

*Ventilator-dependent patients as used above means those who cannot breathe on their own, without assistance from a ventilator.

For your immediate action

Do not stop using your ventilator unless advised by your clinician.

Resmed reinforces the importance of following all instructions in the Astral User Guide.

In particular:

- *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.*

All carers should be appropriately trained, have up-to-date training, and feel confident in responding to alarms and emergency situations. **If you are unsure how to respond to an alarm, contact your healthcare provider or clinician for guidance.**

Ensure that backup ventilation equipment (such as a backup ventilator or manual resuscitator) is available, regularly checked, and ready for immediate use if needed.

What Resmed is doing

Resmed is taking action to address this issue.

Because replacement parts are currently limited, it is not possible to inspect and correct all affected ventilators immediately. Resmed is therefore using a phased approach. Patients who may be at the highest risk if ventilation stops unexpectedly will be prioritised first.

Your healthcare provider will review your individual situation and determine when inspection is required based on your clinical needs and Resmed's phased correction program.

You should continue using your ventilator as directed by your clinician unless you are told otherwise.

Resmed is continuing to increase the availability of replacement parts and evaluate additional correction options for affected ventilators. Further information will be provided if additional action is required.

We appreciate your support in this matter. We consider this action necessary to ensure that all patients continue to receive products of the highest quality. We apologise for any inconvenience this may cause. Your healthcare provider will assess your individual situation and advise you if any changes to your therapy are needed.

If you have any questions or concerns, please contact your local service provider or your treating physician.

Sincerely,

Resmed Quality Assurance and Regulatory Affairs

APPENDIX A

Affected Astral 100 and Astral 150 ventilators and main board spare parts were built prior to October 2024.

If a ventilator has had the main board replaced, review the main board serial number to determine if it is affected.

Summary of affected product breakpoints

Product Type	Serial Number Location	Affected Criteria
Astral ventilator	Device label	Serial number < 22241890149
Main board	Ventilator screen	Characters 2-8 < 2707658

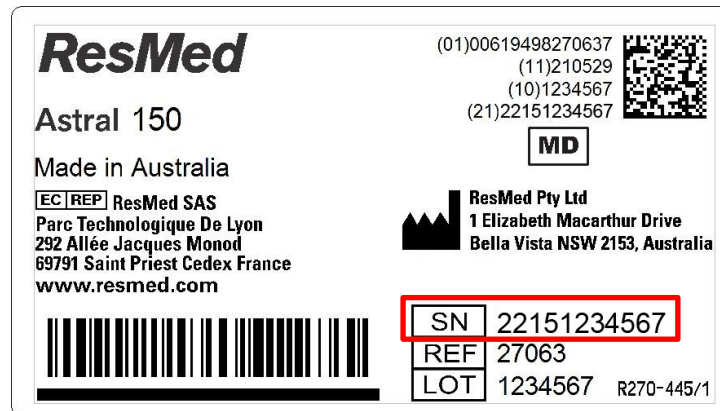
Astral Ventilators

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.



Main Board

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.

