National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

ResMed Astral 100 and 150 Ventilators: Potential for Patient Harm due to Unexpected Interruption of Ventilation Therapy

Date of Issue:	17-Aug-26	Reference No:	NatPSA/2026/004/MHRA

This alert is for action by: all Hospital Trusts, Health Boards and independent healthcare providers delivering NHS, community, home ventilation and private healthcare services.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards).

Explanation of identified safety issue:

ResMed has issued a Field Safety Notice (FSN) regarding Astral 100 and 150 ventilators and associated Printed Circuit Board Assembly (PCBA) spare parts manufactured prior to October 2024. An internal supercapacitor may leak electrolyte, causing damage to specific circuitry of the PCBA and unexpected interruption of ventilation therapy.

If the issue occurs while the ventilator is delivering therapy, ventilation therapy stops immediately; a high priority audible alarm activates, and the user interface may display therapy alarms and a Safety System Fault red screen. If the issue occurs while the device is in standby, a maximum volume alarm activates, and the user interface message may not be displayed. Once the fault occurs, the ventilator becomes inoperable and cannot be restarted. Alternative ventilation is required immediately.

Astral ventilators are used in hospital, community and home settings to provide life-sustaining ventilation for adults and children, including tracheostomy-ventilated, ventilator-dependent and mouthpiece-ventilated patients. Although the reported occurrence rate is low at 0.1% over the device service life of 8 years, interruption of ventilation may result in serious injury or death if an alternative means of ventilation is not immediately available.

Replacement PCBAs are currently subject to global supply constraints. ResMed cannot currently

Actions required

NOTE: Patients should not stop using their ventilator unless they are advised to do so by their clinical team and an alternative means of ventilation is available.

All Actions to be completed by: 17 February 2027

1. Circulate the FSN within **2 working days** to all relevant respiratory, critical care, paediatric, community ventilation and home ventilation services. Ensure relevant staff review and implement the actions described in the FSN.

2. Identify all affected Astral 100 and 150 ventilators and PCBA spare parts manufactured prior to October 2024, including devices used in community and home settings. Refer to **Appendix B** in the FSN to confirm affected serial numbers.

3. Within **1 month** confirm that all affected ventilator-dependent patients have immediate access to a functioning backup ventilator or other emergency ventilation contingency arrangements.

4. Verify and document that carers and relevant staff are trained and competent to recognise ventilator alarms, implement emergency procedures and access urgent clinical support.

5. Clinicians should implement and document a patient-specific clinical risk assessment for all affected patients within **1 month**, prioritising those who:

- require ventilation for ≥14 hours per day
- have a tracheostomy
- are fully dependent on ventilation and/or unable to independently remove ventilation or summon assistance

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: info@mhra.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

provide a definitive timeline for completion of corrective actions across all affected devices. Therefore, available replacements are being prioritised for patients according to highest clinical risk.

Organisations experiencing difficulty obtaining suitable replacement or alternative ventilators should escalate through local procurement arrangements and the DHSC National Supply Disruption Response (NSDR) service where appropriate at: nsdr@dhsc.gov.uk.

- are paediatric or otherwise clinically vulnerable
- use devices approaching or beyond their expected service life
- live in locations where emergency response may be delayed

6. Contact the manufacturer to arrange a date of inspection for the affected devices according to the FSN and local risk prioritisation process.

7. Consider transition to alternative ventilators for patients at highest clinical risk or where devices have exceeded their service life, where clinically appropriate and alternative devices are available.

8. Do not initiate new patients on Astral devices where suitable alternatives are available.

Additional information:

Risks involved in stopping treatment:

Interruption of ventilation therapy may result in serious harm or death. Clinical teams should undertake patient-specific risk assessments before making any changes to treatment. Patients should not stop using affected devices unless advised to do so by their clinical team and suitable alternative ventilation arrangements are in place.

Affected devices:

Astral 100 and Astral 150 ventilators and associated spare parts manufactured prior to October 2024. Use the FSN for identification of affected devices and corrective action instructions.

Key clinical considerations:

- Carers should be trained to recognise and respond appropriately to ventilator alarms and emergency procedures and should be present at all times for patients who are fully ventilator-dependent or unable to independently respond to ventilator failure.
- The most important risk mitigation measure is immediate access to backup ventilation where available.
- Transitioning highly dependent patients to alternative ventilators may be clinically challenging and should be carefully planned.
- Devices approaching or beyond their service life should be reviewed as part of local risk assessments and replacement planning.

Stakeholder engagement:

DHSC National Supply Disruption Response; NHS England National Patient Safety Team; National Clinical Director for Respiratory Disease; Home Mechanical Ventilation Clinical experts; NHS Supply Chain; Devolved Administrations; Cross-system Incident Management Team; International regulators; College of Intensive Care Medicine; British Thoracic Society; British Sleep Society; Interim Devices Working Group.

Report suspected or actual adverse incidents through local reporting systems and the appropriate national reporting route: England, Scotland, Wales, Northern Ireland.

NHS England

Department of Health www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Please check the website for when actions should be ceased or advice to check for date restriction are lifted.