

Early Alert: Resmed Astral Ventilators & PCBA Parts

Purpose of this communication:

We are writing to inform you that ResMed has issued an Early Alert regarding a potential high-risk ventilator issue. The FDA has posted this Early Alert to notify the public while it continues reviewing information and will update its web page as significant new information becomes available.

The issue involves certain ResMed Astral 100 and Astral 150 ventilators that may result in interruption or loss of ventilation support. Patients who rely on ventilatory assistance may be at risk for serious adverse health consequences if therapy is interrupted, particularly those who are ventilator dependent or require continuous respiratory support. Patients should be notified to not stop using the ventilators. They should immediately determine whether the main board currently installed in the ventilator is affected by this issue. Ventilators fitted with a main board that is not affected by this issue are not impacted. Ensure all affected users have backup ventilation equipment available and ready for immediate use while awaiting the correction from Resmed.

As of June 23, Resmed has reported five serious injuries and no deaths associated with this issue.

What do I need to do?

- Please review the [FDA Early Alert](#).
- Notify impacted patients to facilitate repair by the manufacturer according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm whether any CareCentrix patients are affected by this issue. If affected product or impacted patients are identified, notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.