



Astral Field Safety Notice – Total Power Failure alarm issue

PATIENT/CARER LETTER

Reference: Astral-2023-FSN-01

Date: 13 September 2023

Dear Patient/Carer

You have been identified as a patient or carer 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.

It is safe to continue using your Astral ventilator, provided you continue to follow the instructions detailed in the Astral User Guide, with relevant sections contained below as a reminder.

What is the issue?

ResMed's Astral ventilator is designed to sound a Total Power Failure alarm, for at least 2 minutes, when a Total Power Failure occurs. A Total Power Failure occurs when there is no power to the ventilator, from either the internal battery or external power (mains power or external battery). The Total Power Failure alarm alerts the carer that the device has lost power, is no longer ventilating, and action is required to ensure the patient continues to receive ventilation.

It has been identified that a component issue in affected ventilators may cause this alarm to sound for less than 2 minutes, or in some cases, to not sound at all (Note: this alarm is only activated when there is a Total Power Failure).

This issue does not affect the ability of the Astral ventilator to provide ventilation. All other alarms (including low and critically low battery alarms) will function as normal.

To date, there have been no reported serious health effects related to this issue.

Affected Ventilators

Astral ventilators manufactured between 2013 and 2019 are potentially affected by this issue. Refer to Appendix A for information on how to identify when your ventilator was manufactured.

Patient Risk

This issue may affect the duration of the Total Power Failure alarm. Ventilator-dependent patients* may be at risk if a Total Power Failure occurs while ventilating on internal battery only **AND** the duration of the alarm to alert the carer to intervene (restore external power or provide backup ventilation) is reduced.

* Ventilator-dependent patients are those who cannot maintain adequate ventilation without the assistance of a ventilator.



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URGENT FIELD SAFETY NOTICE

Astral 100/150 – Degraded component may lead to Total Power Failure alarm malfunction

Date: 13 September 2023
Reference: Astral-2023-FSN-01
Affected Product: Astral ventilators manufactured between 2013 and 2019
Refer to the Astral ventilator serial number list provided by ResMed

Indications for Use

The Astral 100/150 provides continuous or intermittent ventilatory support for patients weighing more than 11 lb (5 kg) who require mechanical ventilation. The iVAPS mode with optional AutoEPAP is intended for patients weighing more than 66 lb (30 kg). 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's Astral ventilator is designed to deliver a Total Power Failure (TPF) audible alarm for at least 2 minutes to alert the carer/clinician when the ventilator experiences a total loss of power that results in a stop of ventilation. The TPF audible alarm is powered by an electrical component known as a supercapacitor. To monitor performance, this component is tested at each two-year preventative maintenance.

ResMed is bringing to your attention an issue with the performance of the supercapacitor component. This component degrades over time, which may cause the TPF alarm to sound for less than 2 minutes, or in some cases, to not sound at all. This component does not affect any other alarm functionality, including low and critically low battery alarms. This issue does not affect therapy delivery.

To date, ResMed has not received any reports of serious adverse events related to this issue.

Patient harm

When the Astral ventilator is operating on its internal battery, the following scenarios could lead to a TPF and activation of the TPF alarm:

- Complete depletion of the internal battery during use if action is not taken to restore external power (mains power or External Battery) in response to low and critically low battery alarms, or;
- A fault within the Astral ventilator leads to a sudden loss of power with no prior power-related alarms.

A hazardous situation may arise if **all** the following circumstances are met:

1. The Astral ventilator is ventilating while operating on its internal battery, **AND**
2. A TPF occurs on the Astral ventilator, **AND**
3. Due to a degraded supercapacitor, the TPF alarm is unable to provide sufficient warning to the carer/clinician to restore power to the ventilator or to provide an alternate means of ventilation.