



Astral – Managing Degraded Battery Pack

FIELD SAFETY NOTIFICATION

Reference: FSN1608002

Date: August 12, 2016

Distribution: Medical and nursing staff in institutional healthcare facilities.
Health Care Providers (HCP) and Distributors.

Description of issue

ResMed's Astral 100 and Astral 150 have an internal battery that is designed to deliver continuous power when AC power is disrupted or when a patient is mobile (e.g. in a wheelchair). The internal battery is intended to power Astral ventilators for up to eight hours under normal conditions. While the ventilators are operating on internal battery, the "Low battery" alarm is designed to activate when there is 20 minutes of ventilation time remaining and the "Critically low battery" alarm is designed to activate when there is 10 minutes of ventilation time remaining.

Astral ventilators can be used with an external battery (in addition to the internal battery). The Astral External Battery is intended to provide Astral ventilators with an additional eight hours of electrical autonomy under normal conditions. Astral ventilators are also compatible with the RPSII battery.

ResMed has received a small number of reports regarding the performance of the internal battery in the Astral ventilator. Although these reports represent a low percentage (less than 0.1%) of devices sold, it is important that you follow the precautions detailed in this FSN. In these reports, an internal electrical issue has led to ventilation ceasing without either the low battery alarm or the critically low battery alarm being activated. In all of these reported cases the "Total power failure" alarm activated as intended. The risk of this occurring is increased if the internal battery has been charged a high number of times. This issue has also been reported with the Astral External Battery, however there have been no reports of cessation of ventilation when the Astral External Battery is used.

There have been no reports of adverse health effects as a result of this issue.

Patient risk

When Astral ventilators are used with the internal battery as the sole power source, it is important to note that failure of the internal battery could potentially lead to cessation of therapy without the low battery or critically low battery alarm sounding. Under these circumstances, ventilator dependent patients (patients who cannot maintain adequate ventilation without assistance and whose clinical condition rapidly deteriorates) may be at risk if no urgent action is taken to restore power or switch to back-up ventilation.

It remains safe to continue using Astral ventilators, provided patients/carers follow the precautions detailed in this FSN.



Products affected

All Astral 100 and Astral 150 ventilators
All Astral External Batteries
All Astral battery packs (spares)

Note: The RPSII battery is not affected by this notice.

Indications for use

The Astral 100 and Astral 150 device provides continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.

Manufacturer

ResMed Ltd
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Bella Vista 2153
Australia

Actions by ResMed

ResMed has identified product changes designed to address the root cause of the battery issue. Beginning in August 2016, improved battery packs are included in all new Astral ventilators and Astral External Batteries. These devices have serial numbers greater than:

- 22161332346 for Astral ventilators
- 20160748193 for Astral External Batteries

ResMed will begin providing replacement battery packs for all Astral ventilators and External Batteries in use from September 2016.

Actions to be taken by healthcare providers and distributors

- Immediately provide a copy of the attached patient notification to all patients, carers and relevant healthcare providers.
- Complete and return the enclosed reply form.
- ResMed will contact you to arrange supply of replacement battery packs.
- Patients should be contacted to arrange battery pack replacement within their Astral ventilator(s) and Astral External Battery.

Replacement of batteries

- The following patients should have their battery packs replaced as soon as possible and in any event no later than six months from September 1, 2016:
 - Ventilator-dependent patients (i.e. patients who cannot maintain adequate ventilation without assistance and whose clinical condition rapidly deteriorates), or higher dependency patients (e.g. paediatric patients);
 - Patients who regularly rely on internal battery charge.
- All other devices should have their battery packs replaced no later than twelve months from September 1, 2016.
- Battery pack replacement may occur sooner if the ventilator and/or external battery is due for the two year routine maintenance service.



Precautions to be taken by users/carers within the home or healthcare/hospital environment

- Connect the ventilator to AC power whenever possible. In the event of battery failure, connect to AC power immediately to resume ventilation.
- If possible, use an external power source (Astral External Battery or RPSII battery) for ventilator-dependent patients.
- If possible, use an external power source (Astral External Battery or RPSII battery) in mobile situations, including when AC power is unavailable or disrupted. Do not rely solely on the internal battery for mobile use.
- Ensure the external battery source is sufficiently charged before using in mobile situations.
- For ventilator-dependent patients, always have alternate ventilation equipment available, such as a back-up ventilator, manual resuscitator or similar device.
- 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.
- Return the device to a Service Centre if the device displays any notifications of battery issues or significant degradation in battery performance.

We appreciate your support in this matter. We consider this action necessary to ensure that our customers and patients receive products of the highest quality. Please follow all patient and device information presented in the Astral and External Battery User or Clinical Guides.

For any questions, please contact the following ResMed personnel:

