



URGENT FIELD SAFETY NOTIFICATION

Astral battery false fuse activation may lead to power loss

Reference: FSN1706001
Date: June 27, 2017

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

Description of issue

ResMed has received a small number of reports regarding the performance of the internal battery, where the false activation of a fuse leads to shut down of the internal battery. Prior to loss of battery power due to this issue one or more of the following alarms were activated in all reports received to date:

- Battery inoperable
- Power fault / No charging
- Device overheating

If the device is running on external power then ventilation will continue. If the device is not running on external power, or external power is removed, then ventilation will stop with the activation of the total power fail alarm.

There have been no reports to date of any false activation of a fuse in an Astral External Battery. However, if this were to occur while Astral is powered by the external battery, the internal battery in the Astral will provide continuation of power and ventilation and an alarm provides notification that the device is on internal power.

In the highly unlikely event there was simultaneous failure of the internal and external batteries, the device will stop ventilation with the activation of the total power failure alarm. Connection to AC power will enable ventilation to recommence.

To date, 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 any performance issue with the internal battery could potentially lead to cessation of therapy.

Under these circumstances, ventilator dependent patients (patients who cannot maintain adequate ventilation without assistance and whose clinical condition rapidly deteriorates) may be at risk of death or serious injury 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, Astral 100SC and Astral 150 ventilators
All Astral External Batteries
All Astral battery packs (spares)

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

Actions by ResMed

ResMed is updating the User and Clinical Guides to ensure the safe use of Astral ventilators when not on AC power. The labelling for the ventilators is being modified with the following warnings:

The internal battery is NOT intended to serve as a primary power source. It should only be used when other sources are not available or briefly when necessary; for example, when changing power sources.

In the unlikely event of an issue occurring with the external battery, Astral will sound an alarm and notify the user indicating that the device is operating on internal battery power. Ventilation will continue, however, users should connect to an alternative external power source (e.g. AC power) as soon as possible.

In mobile use cases (e.g. wheelchair), an external power source must be connected and used to power the ventilator. The internal battery is designed to deliver continuous power when the external power source is disrupted.

Appropriate use of external power sources mitigates against the risks associated with the unlikely occurrence of a battery performance issue.

Furthermore, ResMed will provide a warning sticker to be attached to ventilators.

Actions to be taken by carers

Please continue to follow all patient and device information in the Astral User and Clinical Guides, in particular, the following warnings:

- 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.

ResMed also reminds users to ensure that Astral ventilators and External Batteries are returned to a service centre for routine two year maintenance which includes a scheduled battery replacement.

Once available, affix the warning sticker to your ventilator



In the event of an issue with either the internal or external battery,

1. Carers should connect to AC power, or alternative power source immediately.
2. Ensure your backup source of ventilation is available and ready for use if necessary.
3. Immediately contact your Health Care Provider or authorised ResMed Service Centre to arrange battery replacement.

Actions to be taken by distributors and healthcare providers

- Keep the attached Clinical Guide addendum with all existing Clinical Guides
- Immediately provide a copy of the attached Patient Notification letter and User / Clinical Guide addendum to all patients, carers and relevant healthcare providers.
- Complete and return the enclosed reply form
- Once available, affix the warning sticker to your Astral devices
- Distribute the warning sticker to patients, carers and relevant healthcare providers

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.

For any questions, please contact ResMed Technical Support:

Technical Services
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Sincerely,

A handwritten signature in cursive script that reads "Linda Laidlaw".

Linda Laidlaw
Vice President Global Quality Assurance & Regulatory Affairs



Reply form to the field safety notification “Astral battery false fuse activation may lead to power loss”

To enable compliance to regulatory action traceability requirements, please complete this confirmation form in full and send it back to us by e-mail or post mail as soon as possible:

Technical Services
ResMed (UK) Ltd
96 Jubilee Avenue
Milton Park, Abingdon, OX14 4RW
astralbatterysupport@resmed.com

Name & Address of Health Care Facility / HCP / Distributor:

I confirm receipt of this field safety notification and I confirm that I have read and understood its content. I have forwarded this information as appropriate.

Name

Position

Signature

Date
