



Astral – Labelling Update

FIELD SAFETY NOTIFICATION

Reference: FSN1706001
Date: June 8, 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 the issue occurring, 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. Reconnection to external 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 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 warning:

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 mobile use cases (e.g. wheelchair), an external power source should 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.

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.

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.

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 your local ResMed Representative

Dimitrios Nasis
Phone : +30 210 876 4817:
Email: astralbatterysupport@resmed.com.

Sincerely,

Linda Laidlaw
Vice President Global Quality Assurance & Regulatory Affairs



Reply form to the field safety notification “Astral – Labelling Update”

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

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



Astral – Labelling Update

PATIENT/CARER LETTER

Reference: FSN1706001

Date: June 8, 2017

Dear Patient / Carer

I'm writing to you with some important information about your Astral ventilator. Patient safety is ResMed's highest priority and it is important that you read and understand this letter.

Update to the Astral User Guide

ResMed is updating the Astral User Guide to ensure the safe use of Astral ventilators when not connected to AC power. The User Guide is being modified with the following warning:

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.

Actions to be taken:

- Please read and ensure you understand the User Guide addendum
- Keep the attached User Guide addendum with your Astral User Guide
- If you have any questions or concerns about this letter or your Astral device please contact your local service provider or treating physician

Description of issue

ResMed has received a small number of reports regarding the performance of the internal battery. This issue has the potential to result in the Astral device stopping when it is not connected to external power. If the device is running on external power then the 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. Reconnection to external power will enable ventilation to recommence.

To date, there have been no reports of injury as a result of this issue.

What this means for you

It remains safe to continue using Astral ventilators, provided patients/carers follow the precautions detailed in this letter and the attached User Guide addendum.

When away from AC power, use of external power sources in accordance with this letter reduces the risks associated with the rare occurrence of a battery performance issue.



Please continue to follow all patient and device information in the Astral User Guide, including 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.

Products affected

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

We appreciate your support in this matter. Patient safety is ResMed's highest priority and it is important that you read and understand this letter.

Sincerely,