URGENT FIELD SAFETY NOTIFICATION

Stellar 100/150 – Device failure may lead to alarm malfunction

Date
5 December 2019

Product description

The Stellar 100/150 is not a life support ventilator.

The Stellar 100/150 is intended to provide ventilation for non-dependent, spontaneously breathing adult and paediatric patients (13 kg and above) with respiratory insufficiency, or respiratory failure, with or without obstructive sleep apnoea. The device is for noninvasive use, or invasive use (with the use of the ResMed Leak Valve). Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage. The Stellar is contraindicated in patients who are unable to endure more than brief interruptions in ventilation.

Description of issue

ResMed received a confirmed case of an alarm buzzer not working under the following circumstances:

- The device has a failed electronic component and,
- The device is stored without AC power connected for more than 36 hours leading to full depletion of the battery and,
- The device powers on automatically when connected to AC power without pressing the power switch.

The identified issue is a combination of software and a component failure that may occur in a small number of devices. If a device with this issue is used in the condition described above, the audible alarms may not operate properly. Alarms will display on the screen of the Stellar device. If the device is used on a ventilator dependent patient, an alarm or failure condition may present a risk of injury or even death.

Devices manufactured between April 2016 and June 2017 are affected by this issue.

ResMed is issuing this notification to help users identify when their device may not be functioning properly and to reinforce the basic instructions and functional tests from the Stellar User Guide.

Reinforcing of Stellar 100/150 user instructions

Stellar should be used consistent with the indications for use.

Perform a functional test including alarms as described in the 'Starting therapy' section in the User guide prior to each use. Press the power switch at the back of the device once to turn on the device.

Check that the alarm sounds a test beep and the LEDs (visual indicator) for the alarm signal and the Alarm mute button flash. Stellar remains safe for use when used as indicated and following the user guide. Refer to Appendix A for details.

Products affected

This Field Safety Notification is relevant for Stellar 100 and 150 devices manufactured between April 2016 and June 2017 within the following serial number range: 20160123307 to 22171057208.

A detailed list will be provided to customers with affected product.

Actions by ResMed

ResMed is developing a device correction to address this issue. When this is available ResMed will contact affected customers with specific actions at that time. Stellar remains safe for use when used as indicated and following the user guide.

Actions to be taken by healthcare professionals and users

The Stellar is contraindicated in patients who are unable to endure more than brief interruptions in ventilation. It is important to assess changes in a patient's dependence on mechanical ventilation, particularly if their condition is progressive. If a patient is ventilator dependent, consider consulting their physician to discuss changing the patient to an appropriate device such as a life support device.

Please continue to follow all patient and device information in the Stellar User and Clinical Guides, in particular, the following sections (See Appendix A):

- Performing a functional test
- Working with alarms
- Internal battery
- Mobile use

As always, if there are any concerns regarding Stellar device behaviour and operation, please contact your local ResMed customer service contact to organise a service.

Actions to be taken by distributors and healthcare providers

Please forward this notice to your affected customers and physicians.

We appreciate your support in this matter. We consider this action necessary to align with our commitment to provide to our customers and patients products of the highest quality.

For any questions, please contact technical.service.support.eu@resmed.com

Sincerely,

Dawn Haake
Vice President Global Quality Assurance & Regulatory Affairs

Appendix A

Instructions for safe usage of Stellar 100/150 – Extract from Stellar User Guide

Performing a functional test

Make sure your device is functioning properly each time before starting therapy.
If any problems occur, see “Troubleshooting”.

1. **Turn off the device by pressing the power switch at the back of the device.**
2. **Check condition of device and accessories.**

   Inspect the device and all the provided accessories. If there are any visible defects, the system should not be used.
3. **Check the circuit configuration.**

   Check the integrity of the circuit configuration (device and provided accessories) according to the setup descriptions in this User Guide and that all connections are secure.
4. **Turn on the device and check alarms.**

   Press the power switch at the back of the device once to turn on the device.

   Check that the alarm sounds a test beep and the LEDs (visual indicator) for the alarm signal and the Alarm mute button flash. The device is ready for use when the *Treatment* screen is displayed. If the display shows the *Reminder* page, follow the instructions, then press to display the *Treatment* screen.
5. **Check batteries**.

   Disconnect the device from the mains and external battery (if in use) so that the device is powered by the internal battery. Check that the Battery use alarm is displayed, and the battery LED is on.

   Note: *If the charge state of the internal battery is too low, or if the battery is empty, an alarm occurs. See the Alarm troubleshooting section for further information.*

   Reconnect the external battery (if in use) and check that the LED for the external power supply is lit. The External DC power use alarm will be displayed and the Alarm LED will light.

   Reconnect the device to the mains.
6. **Check H4i heated humidifier (if in use).**

   Check that the warm-up feature is displayed in the *Treatment* screen. Start the warm-up feature. Check that the humidifier warm-up symbol is displayed on top of the screen.

   Note: *The H4i in heating mode can only be used when the device is connected to mains supply.*

Working with alarms

WARNING

- **This device is not intended to be used for vital signs monitoring. If vital signs monitoring is required, a dedicated device should be used for this purpose.**
- **When adjusting the alarm volume, ensure that the alarm can be heard above the ambient noise levels that the patient may experience in a variety of settings, including use in noisy environments or inside mobility bags.**

This device is fitted with alarms to alert you to changes that will affect your treatment.

Internal battery

CAUTION

Over time, the capacity of the internal battery will decrease. This depends on individual use and ambient conditions. As the battery degrades, the battery charge level indicator may lose accuracy. This will mean battery-related and system alarms may not activate as intended. ResMed recommends the battery be tested after two years to assess the remaining battery life. Testing and replacement of the internal battery should only be performed by an authorised service agent.

The power status of the battery is displayed on top of the LCD screen. Check the battery status regularly while operating the device with the internal battery and connect the device in time to mains power or alternatively to the external battery. Additionally, the Internal battery use alarm will be displayed.

Mobile use

For extended mobile use, the ResMed Power Station II external power supply unit can be used as an additional power source.