

December 27, 2019

Re: Urgent Field Safety Notification
Stellar 100/150 Device failure may lead to alarm malfunction

Dear Ontario Ventilator Equipment Pool (VEP) client, parent, caregiver, substitute decision maker (SDM):

The VEP received notification on December 20th 2019 from ResMed Inc. of an Urgent Field Safety Notification. Please find a copy enclosed herein. You are receiving this letter because our records indicate you have a model ResMed Stellar150 bilevel device with a serial number in the affected serial number range.

Description of the Issue:

ResMed Inc. 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.

What to do:

Please read the attached Field Safety Notification and follow the instructions provided by ResMed Inc. ResMed Inc. has issued 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. Appendix A, enclosed, is an extract from the Stellar User Guide detailing how to perform a functional test. Make sure your device is functioning properly each time before starting therapy. If you require assistance with performing a functional test please call the VEP during business hours Monday through Friday from 0900 to 1700 at 1-800-633-8977 for phone support by our Respiratory Therapist.

What to do if the device does not pass the functional test:

If your device does not perform as intended after performing the functional test, please provide alternate source of ventilation to the user and notify the VEP at 1-800-633-8977 to arrange for a replacement device.



If there is a medical emergency please call 911.

ResMed Inc. has notified the Ontario Ventilator Equipment Pool they are developing a solution to correct the performance issue of this device. When this correction becomes available, the VEP will contact you to arrange for service to your device.

Should you have questions regarding this notification, please do not hesitate to contact me directly at 1-800-633-8977 or by email at Regina.Pizzuti@Kingstonhsc.ca

Kind regards,

Regina Pizzuti, RRT, BA
Manager, Ontario Ventilator Equipment Pool

Health Canada Recalls & Safety Alerts.
<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/71937r-eng.php#affected-touches>