carecentrix

Provider Newsflash Feb. 19, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued a Class 1 recall of Stellar model 100 and 150 Non-invasive and Invasive Ventilators with serial numbers ranging from 20160123307 to 22171057208 manufactured from April 2016 to June 2017 and distributed from April 2016 to November 2017 because the sound alarm may fail to work if:

- The device has a failed electronic part
- The device is stored without AC power connected for more than 36 hours letting the battery drain completely, or
- The device powers on automatically when connected to AC power without pressing the power switch

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/medical-devices/medical-device-recalls/resmed-recalls-stellar-100-and-150-non-invasive-and-invasive-ventilators-due-sound-alarm-failure?utm_campaign=FDA%20MedWatch%20Stellar%20100%20and%20150%20Non-invasive%20and%20Invasive%20Ventilators%20by%20ResMed&utm_medium=email&utm_source=Eloqua
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by:
    - Faxing information– To: 919-792-6718 Attn: Quality Department

Thank you for your prompt attention and cooperation in this matter.