

FDA Recall – Baxter Healthcare Corporation

Purpose of this communication:

- We are writing to inform you that Baxter Healthcare Corporation is correcting the Life2000 Ventilator System due to a nonconforming battery charger, which triggers a battery alarm and renders the ventilator inoperable. This is a result of a failed crimping operation during manufacturing that caused the crimp to puncture the insulation of the charger connector, thus resulting in an audible and visual alarm, which when engaged makes the ventilator inoperable.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/continuous-ventilator-correction-baxter-healthcare-corporation-issues-correction-life2000-ventilator?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the battery charger replacement, 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 in advance for your cooperation and continued partnership.