

January 2024

Subject: Important OPTIMIZER[®] communication to address inappropriate suspension of CCM[®] therapy if a charging error occurs.

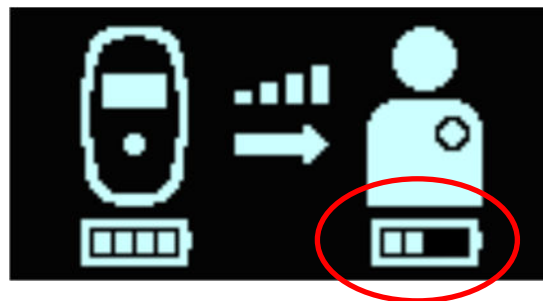
Summary

- Impulse Dynamics has identified that approximately 1.6% of implanted OPTIMIZER devices may incorrectly interpret that charge current is high during a regular device safety self-check, resulting in the device displaying a charging error. The result is that the device enters Safe Mode which suspends CCM therapy and charging until the device can be reset by either a physician or Impulse Dynamics representative.

Impulse Dynamics has received reports of 18 devices that have experienced this behavior out of more than 1,160 impacted OPTIMIZER implants. As of December 1, 2023, we have received no reports of harm to patients when this error causes CCM therapy suspension.

Affected devices may experience repeat charging error causing Safe Mode upon recharging to 100% of battery capacity. It appears that limiting charging to 75% is effective in averting further charging errors and CCM therapy suspension. **There does not appear to be a test or sign or lot number to predict which susceptible model CCM X11 devices will experience suspension of CCM therapy.**

- Impulse Dynamics recommends all patients with implant card showing model CCM X11, who have experienced one or more charge errors (indicated by the display of “A9” on their charger), charge their implanted device to no more than 75% of full capacity. To accomplish this:
 1. During weekly charging, monitor the charging feedback screen (shown below) displayed on the Vesta/Guardio charger.



Impulse Dynamics Communication to address inappropriate suspension of CCM® therapy

2. Pay particular attention to the implanted device's battery charge indicator, which we have circled in red in the figure.
3. Stop charging when you notice the leftmost 2 bars are solid (as indicated in the figure). There will be a third, adjacent bar blinking.

Checking the feedback screen every 5 to 10 minutes is sufficient to avoid charging over 75% and potentially triggering another "A9."

- Impulse Dynamics plans to launch a software fix for this issue as soon as regulatory approval is obtained. The software update will be delivered during a future office visit. The fix is expected to eliminate this issue completely and allow this subset of affected patients to proceed with normal charging to 100%.
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