

URGENT MEDICAL DEVICE REMOVAL**29901 CareLink Encore™ Programmer Power Supply Model 26907**
(See Appendix A for List of Programmer Serial Numbers)

January 2019

Dear Risk Manager or Health Care Professional:

This letter is to inform you of the potential for an electrical short circuit to develop in a subset of 479 Model 26907 power supply cable plugs that connect to the Medtronic Model 29901 CareLink Encore programmer. A failure mode of the power supply has been found where an electrical short occurs on the low voltage direct current connector and results in the connector heating up, generating smoke, melting and in some cases disconnecting from the programmer. Note that Encore programmers are designed with a battery back-up power source which can support programmer operations with at least 20 minutes of power prior to shutting down the programmer.

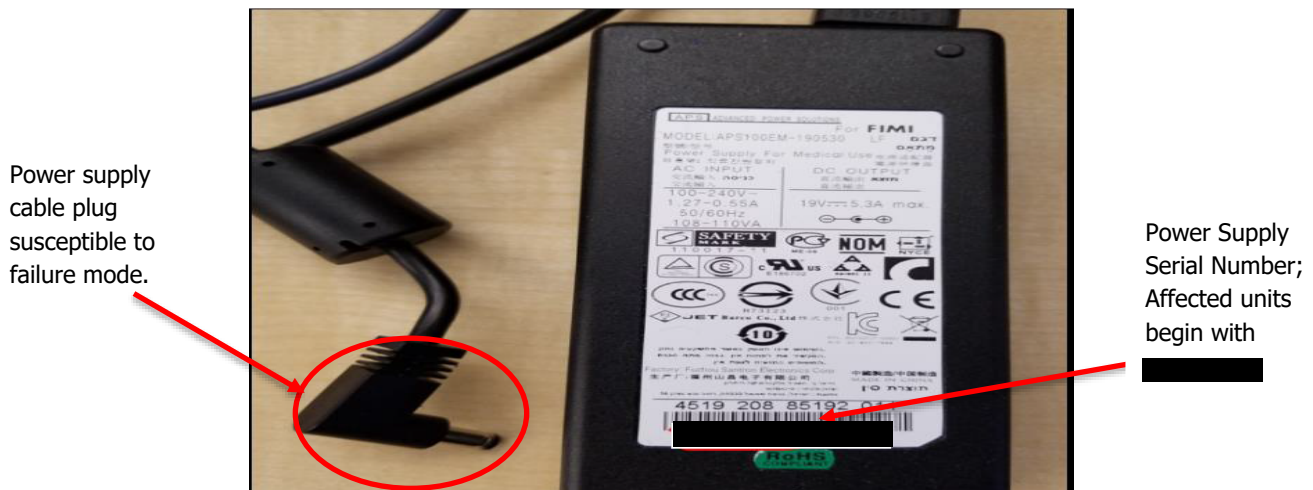
Your local Medtronic representative has identified there is an affected Model 26907 Power Supplies in your clinic/hospital.

Background Information

Through January 09, 2019 Medtronic has identified 14 complaints potentially related to electrical shorting within the identified subset of 479 power supply units associated with Encore programmers. Medtronic has identified zero (0) reports of patient or user harm as a result of this issue. Potential harms related to an electrical short include temporary burn or injury if a customer or patient comes into close physical contact of the cable plug while the short is actively heating the cable plug. Loss of power to the programmer is mitigated by the presence of the back-up battery power source in each Encore programmer.

The affected power supplies were potentially packaged with a subset of Model 29901 CareLink Encore Programmers distributed in the US, India and specific countries in Europe, and the Middle East. Each affected power supply has a serial number beginning with [REDACTED] (refer to Figure 1). The potential for an electrical short circuit to develop in the cable plug is specific to this subset of power supplies. Encore programmer power supply units outside of the identified serial number list are not in scope of this advisory and will not be replaced. Model 26907 power supplies are not compatible with other Medtronic programmers (e.g. CareLink™ Programmer Model 2090).

FIGURE 1



Your local Medtronic representative will take responsibility for identifying and replacing any affected power supply with a new unit and will notify you when the action has been completed.

If no affected power supply units are found at your hospital/clinic, or after your Medtronic representative has notified you that they have already replaced any affected power supplies, no further actions are required.

Until your local Medtronic Representative is able to provide a replacement power supply for the identified Encore programmer(s) in your possession, please follow the Customer Actions noted below.

Customer Actions

If affected Power Supply units are identified at your hospital/clinic, Medtronic recommends customers take the following actions until your Medtronic representative has notified you that the affected unit has been replaced:

- Continue to use your Model 29901 Encore programmer to conduct patient follow-up sessions as described in the instructions for use (IFU) labeling. If no electrical short circuit has developed, your power supply cable is safe to use.
- Discontinue use of any power supply immediately if you observe overheating, smoke or melting near and around the power supply cable plug to the programmer (refer to Figure 1). Notify your local Medtronic representative or Medtronic Technical Services to report the observed failure.
 - The back-up battery in the programmer can continue to sustain programmer operations for any active session for at least 20 minutes to allow you time to safely complete the programmer session and reprogram a device if necessary.
 - If available, attach an alternate power supply Model 26907 to the existing Encore programmer, or obtain an alternate Encore or Model 2090 programmer. This will allow you to conduct patient follow-up sessions until your local Field Representative can provide a replacement power supply.

Please share this notice with all individuals who need to be made aware within your organization, or to any organization where potentially affected power supplies may have been transferred.

Medtronic will notify all applicable regulatory agencies about this matter, including the FDA.

Adverse reactions or quality problems experienced with this product may be reported to FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax:


- Complete and submit the report online at <http://www.fda.gov/medwatch/report.htm>
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For questions related to this notice or 29901 CareLink Encore Programmer service, please contact your Medtronic representative, or for technical questions, please call Instrument Technical Services at 800-638-1991.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. We appreciate your prompt attention to this matter.

Sincerely,

Appropriate Medtronic Representative, e.g. VP of Quality, VP of Medical Affairs, etc.



Chris Harrold
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm & Heart Failure