

URGENT MEDICAL DEVICE CORRECTION

CADD-Solis™ AC Adapter Model 21-0270-25

26 June 2024:

Dear Valued CADD-Solis Customers:

- Director of Biomedical Engineering
- Director of Nursing
- Director of Risk Management

Smiths Medical is issuing this letter to notify you of a potential issue with the AC Adapter used with the CADD-Solis Ambulatory Infusion Pump, which may be used as an alternative to battery power and for recharging the optional CADD-Solis rechargeable battery pack.

Overview of the Issue:

The AC Adapter input plug, highlighted in Figure 1 below, can become damaged or broken. If the input plug is damaged, the metal contacts to the body of the AC Adapter may be exposed or one or more of the AC mains prongs may separate from the input plug.



Figure 1: CADD- Solis AC Adapter

Potential Risk:

If the AC Adapter is damaged, exposure to electric current may potentially lead to burns or electrical shock. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:

This issue affects the AC Adapter (P/N 21-0270-25) released in February 2018.

Required Actions for Users:

1. Locate all Model 21-0270-25 AC Adapters in your possession. Inspect the AC Adapter for damage to the input plug, missing AC prongs, or exposed metal contacts. Refer to Figures 2 and 3 below for examples of damaged AC Adapters. If damaged, remove the AC Adapter from service and submit a request for credit to Smiths Medical at 800-258-5361.
2. If the AC Adapter is damaged while it is plugged into an AC Mains outlet, notify your biomedical engineering department to assist in removing the plug.
3. Complete and return the attached Response Form to smithsmedical8528@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification, even if you do not have the affected product.
4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to smithsmedical8528@sedgwick.com.



Figure 2: Damaged Input Plug



Figure 2: AC Adapter with Missing AC Prong

Follow up Actions by Smiths Medical:

Smiths Medical is sending this notification to all affected CADD-Solis customers and is making replacement AC Adapters available to you. Smiths Medical evaluated the current design of the AC Adapter and is in the process of qualifying an improved design. We will notify you when the improved design is released commercially.

For further inquiries, please contact Smiths Medical using the following information:

| Smiths Medical Contact | Contact Information | Areas of Support |
|-----------------------------|--|---|
| Global Complaint Management | globalcomplaints@icumed.com 1-(866)-216-8806 | To report adverse events or product complaints |
| Technical Support | TSC.Support@icumed.com 1-800-241-4002, option 3, 4 (M-F, 8:00 am – 6:00 pm CT) | Additional information or technical assistance, |
| Field Corrections | icumed.custhelp.com/app/market-action | Questions about this Field Correction Notice |

This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1-(888)-INFO-FDA

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jim Vogel".

Jim Vogel
Vice President of Quality

Enclosures:

- Response Form (separate document)