



Edwards

URGENT FIELD SAFETY NOTICE

ADDENDUM

FCA #128

EV1000

Model Numbers: EV1000A, EV1000NI

Lot Numbers: All lots for models listed

<MM DD, YYYY>

<Customer #>

<Contact name or Dept.>

<Firm Name>

<Attention: RISK MANAGEMENT>

<Address>

<City/state/zip>

Dear Valued Customer:

This letter is in follow-up to our initial communication regarding EV1000 monitors and the risk associated with smoke, sparks or fire related to the power supply.

In our initial communication, we noted that improper mounting of the power supply could result in liquid ingress into the adaptor causing a short with the potential to lead to a possible fire hazard. This letter is to inform you of additional potential causes, our plans to address the issues, and steps you can take to help minimize risk.

Reports of Burnt Cables:

- We have reports of cables that appear burnt, without smoke, sparks or fire. We continue to investigate to identify all potential causes. One potential cause is the presence of conductive material in the AC inlet of the power supply.
- Please assure that there is no conductive material in or near the AC inlet when connecting the AC power cord to the EV1000 power supply, and that both the AC power cord and inlet are clean and dry.

Reports of Smoke, Sparks or Fire due to Cleaning or Decontamination/Disinfection:

- The product instructions indicate that product should be kept dry and the cables should not be immersed in any liquid solution or liquids allowed to penetrate connectors.



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- Another opportunity for liquid ingress into the power supply could be the cleaning and disinfection process. Although the cleaning instructions in the EV1000 Operators Manual indicate both to only wipe with a damp cloth and to dry the cable after cleaning, user reports indicate that this process is not always followed.
- Please assure that the cleaning instructions as noted in the EV1000 Operators Manual are followed, and that the AC power cord and inlet are clean and dry prior to use.

Edwards is working to address all of the root causes, and to implement actions on units already in the field as quickly as possible.

These actions include:

- Updated customer notification of all potential causes and mitigations, including ensuring the AC power cord and inlet are kept clean, dry and free of contamination by conductive materials prior to use. (completed with this notification).
- Updating the Operators Manual to include the instructions as noted above and any others identified as our investigation continues (in progress).
- Visiting your facility to (1) apply a label to the AC power cord to help assure proper orientation to avoid liquid ingress, and (2) confirm that the area is clear of potential contaminants.
- Implementation of design changes that would eliminate or reduce the potential for liquid ingress and other potential contaminants (identification in progress).

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions, please contact **Edwards Customer Service or Tech Support at <phone>**

Sincerely,

Michael Collins
Vice President of Quality, Critical Care

This Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant competent authority.



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CUSTOMER ACKNOWLEDGEMENT

<Contact name or Dept.>

<Firm Name>

<Attention: RISK MANAGEMENT>

<Address>

<City/state/zip>

Please follow all instructions below to complete the acknowledgement process.

Complete this acknowledgement form to confirm that you received this addendum:

- DO NOT return any product
- Email the completed form to Edwards Tech Support at tech_support@edwards.com, within 10 days from receipt of this notification

Name (Print):	
Title/Dept.:	
Firm Name:	
Telephone Number:	
Signature:	
Date:	

**Please return this form via email to Edwards Tech Support at tech_support@edwards.com
Support at: <phone>**