



Edwards

## **OPERATOR'S MANUAL CLARIFICATION PRODUCT NOTIFICATION- ACTION REQUIRED**

Subject: Safety Notice EV1000A Shock and Fire Hazard, Model Number: EV1000A

Month/date/year

<Contact name or Dept.>

<Firm Name>

<Address>

<City/state/zip>

Dear Valued Customer:

This is to inform you of a voluntary safety notice regarding the EV1000A system to reinforce the proper set up of the external power supply according to the equipment operator manual. Edwards Lifesciences has recently been notified about an electrical fire that initiated at the power supply of one of the EV1000A system due to noncompliant system installation configuration which caused fluid ingress to the power supply. Edwards Lifesciences is not removing product from commercial distribution.

We are informing all customers with EV1000A systems to confirm compliance of installation configuration against the current requirements documented in the Operator's Manual section EV1000 Power Adapter Mounting Bracket.

This is a reminder that the EV1000A Operator's Manual warns about immersion of the device or its components and warns against letting fluid enter the device (Reference is included in the Warning and Caution section of the Operator's Manual) and that the external power supply for the EV1000A should be installed as illustrated in the operation manual (Figure 15-8 EV1000 Power Adapter Bracket and Figure 15-9 EV1000 Power Adapter Bracket included in the Operator's Manual) where the AC Cord plugs into the power supply, exactly as shown in the illustrations in the operators manual.

Please take this opportunity to review the EV1000A system configurations at your site to ensure they are configured as Operator's Manual, to minimize the risk of fluid ingress as possible in the account's environment.

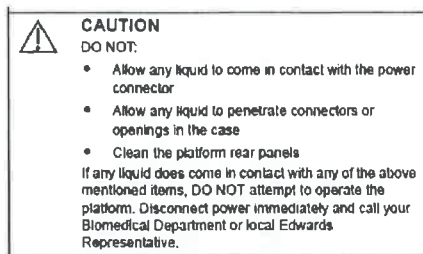
### **Reference Warnings and Caution Section from Operators Manual**



#### **WARNING**

Shock or fire hazard! Do not immerse the EV1000 monitor, Databox or cables in any liquid solution. Do not allow any fluids to enter the instrument.

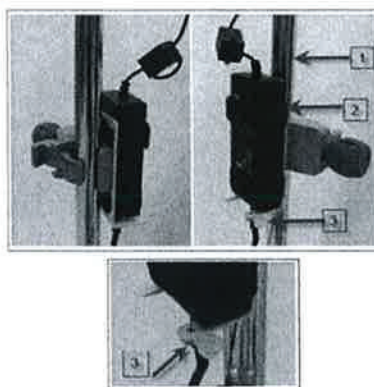




**Figure from EV1000A Operators Manual on Power Adapter Orientation (Figures 15-8 and 15-9)**



**Figure 15-8 EV1000 Power Adapter Bracket**

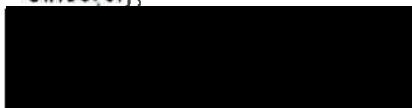


**Figure 15-9 EV1000 Power Adapter Bracket**

Details of steps 1, 2, 3  
are included in the  
Operator's Manual

At Edwards Lifesciences, we are committed to helping you advance the care and treatment of surgical and critical care patients. This commitment extends to the products, service and support we provide. We apologize for the inconvenience caused by this action and appreciate your attention to this matter. If you have additional questions, please call Edwards Customer Service at XXXXXXXXXX

Sincerely,



Mark Gayle, Vice President of Quality, Critical Care



**Acknowledgment Form  
EV1000A**

<Customer #>  
<Contact name or Dept.>  
<Firm Name>  
<Address>  
<City/state/zip>

Please call **Edwards Customer Service at XXXXXXXX** (5:00AM PDT to 4:30 PM PDT)  
if you have any questions.

Our record show you currently have the following S/N's at your site:

Product Code	Serial Number
EV1000A	

Please check the appropriate box below as soon as possible and **FAX** the completed  
form to **Edwards Customer Service at XXXXXXXX**

- ☐ Yes. The EV1000A system(s) is/are configured as specified within the operation  
manual.  
☐ No. The EV1000A system is NOT configured as specified within the operation manual.  
Assistance Needed.  
☐ I don't know. Assistance Needed.

Name (Print): \_\_\_\_\_

Signature: \_\_\_\_\_

Title and Department: \_\_\_\_\_

Contact Info.: / Tel. No. / Fax No. / Email: \_\_\_\_\_

Date: \_\_\_\_\_

