



Edwards

OPERATOR'S MANUAL CLARIFICATION URGENT FIELD SAFETY NOTICE

EV1000A Reference # FCA-77

Date: 03 May 2016

Attention: ////////////////

Details on affected devices:

EV1000A Monitor is used to optimize fluid management through the use of minimally invasive monitoring with the FloTrac sensor (or the Volume View sensor). The EV1000A System consists of:

- EV1000 Panel
- Databox
- Power Supply (external to Panel and Data Box)
- Cables to connect the components

Description of the problem:

Edwards Lifesciences has initiated a voluntary safety alert regarding the EV1000A system to reinforce the proper set up of the external power supply according to the equipment's operator manual.

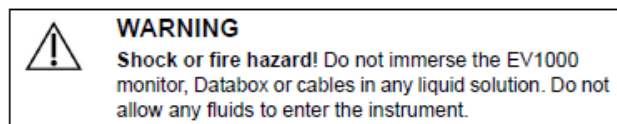
The company received a recent event of an electrical fire, therefore is sending this notice to all customers with EV1000A systems installed to confirm installation against the current requirements documented in the Operator's Manual section EV1000 Power Adapter Mounting Bracket.

Advise on action to be taken by the user:

All the EV1000A system installed are within the scope of this action, this is a reminder that the EV1000A operators 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 down 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, as shown in the illustrations.

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

Reference Warnings and Caution Section from Operators Manual





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	<p>CAUTION DO NOT:</p> <ul style="list-style-type: none">• Allow any liquid to come in contact with the power connector• Allow any liquid to penetrate connectors or openings in the case• Clean the platform rear panels <p>If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the platform. Disconnect power immediately and call your Biomedical Department or local Edwards Representative.</p>
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Figure from EV1000A Operators Manual on Power Adapter Orientation (Figures 15-8 and 15-9)



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Figure 15-8 EV1000 Power Adapter Bracket

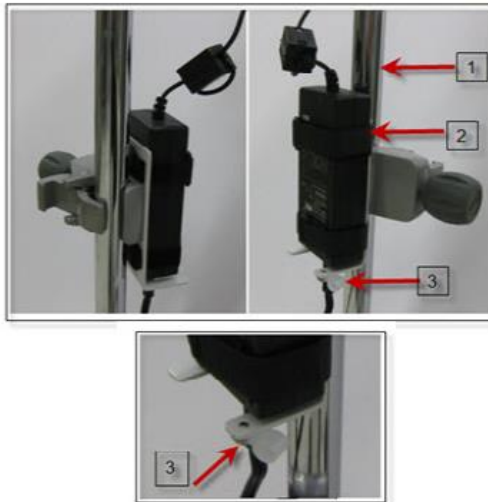


Figure 15-9 EV1000 Power Adapter Bracket

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 the local Edwards Customer Service.

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

Sincerely,



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**EV1000A
Reference # FCA-77**

A handwritten signature in black ink, appearing to read 'Andleeb Arshad'.

Andleeb Arshad
Regulatory Affairs Manager UK, Ireland and Nordics
Edwards Lifesciences



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**EV1000A
Reference # FCA-77**

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

Please call the local **Edwards Customer Service** 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 return the completed form to the local **Edwards Customer Service**.

- Yes. The EV1000A systems 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: _____

Section below to be completed by Edwards, in case customer indicates "Assistance Needed":



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**EV1000A
Reference # FCA-77**

- Date for customer visit:
- Name and Surname of EW person visiting the customer:
- Signature and Date of EW person visiting the customer:

By the signature above it is confirmed that EV1000A system is configured as specified within the operation manual.