



URGENT MEDICAL DEVICE SAFETY NOTIFICATION – ACTION REQUIRED

Field Corrective Action #128

Product: EV1000 clinical platform

Model Numbers: EV1000A, EV1000NI, EV1000CS

Lot Numbers: All lots for models listed

March 08, 2019

Attention: RISK MANAGEMENT

cc: Chairman Medical Board and relevant Head of Departments

Dear Valued Customer:

As part of our strong commitment to quality, we continuously monitor our products throughout their life cycle to quickly identify and correct any potential issues. We recently became aware of an issue with Edwards EV1000 clinical platform, and are notifying our customers.

Description and indication of product:

The EV1000 clinical platform is used to optimize fluid management through the use of minimally invasive or non-invasive monitoring technologies.

The EV1000A system consists of the following components to monitor a patient using minimally invasive technology:

- Monitor
- Databox
- Power adaptor

The EV1000NI system consists of the following components to monitor a patient using non-invasive technology:

- Monitor
- Pump Unit
- Pressure Controller
- Heart Reference Sensor (HRS)

The EV1000CS is a virtual bundle composed of EV1000A + EVNIUPG models. The system consists of the following components to monitor a patient using both minimally invasive non-invasive technologies:

- Monitor
- Databox
- Pump Unit
- Pressure Controller
- Heart Reference Sensor (HRS)

Description of the problem:

Edwards Lifesciences has identified a potential risk, which may occur during the use of the EV1000 clinical platform with minimally invasive and non-invasive technologies. Edwards



Lifesciences has received a limited number of reports regarding fluid ingress into the AC power outlet on both the EV1000A power adaptor and the EV1000NI pump unit.

This is a voluntary safety notice regarding the EV1000 clinical platform to reinforce the proper set up of the external power supply according to the equipment operator manual. Edwards Lifesciences has been notified about the potential for an electrical short circuit leading to a possible fire hazard due to liquid ingress. This issue was noticed at the AC cord of an EV1000 clinical platform due to incorrect orientation. **Edwards Lifesciences is not removing product from commercial distribution.**

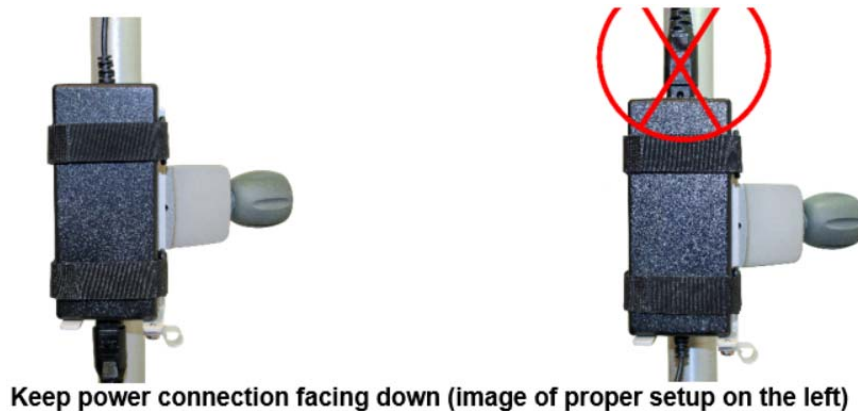
Based on review of previous instances, we strongly advise you to be cautious that IV bags and other fluids need to be positioned away from AC power connectors in order to avoid liquid ingress.

For EV1000A clinical platform installations:

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

This notification 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).

The external power supply for the EV1000A should be installed as illustrated in the Operator's 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.



Keep power connection facing down (image of proper setup on the left)



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.
	CAUTION DO NOT: <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 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.

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



Figure 15-8 EV1000 Power Adapter Bracket

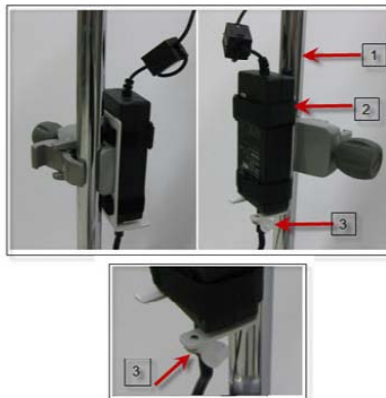
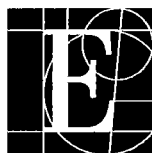


Figure 15-9 EV1000 Power Adapter Bracket

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

See illustration for set up from the wall outlet to power supply at the bottom of power adapter (3) as per the illustration of figure 15-9.



Edwards

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

For EV1000NI clinical platform installations:

We've received reports where liquid is dripping on to the unit which may lead to an electrical short circuit leading to a possible fire hazard due to liquid ingress. Unlike the EV1000A, the EV1000NI AC cord inserts horizontally into the unit. Therefore, orientation is not a factor of liquid ingress. However, in case of excessive liquid exposure, the unit may short circuit leading to a possible fire hazard due to liquid ingress at the AC cord.

We strongly advise you to be cautious that IV bags and other fluids need to be positioned away from AC cord in order to avoid liquid ingress.

Please complete the enclosed response form so we may follow up with any further actions as necessary.

If you have any questions, please contact **Edwards Customer Service or Tech Support at +65 9658 4570.**

Sincerely,



Sunita Das
Director | Quality Assurance
Edwards Lifesciences