



Edwards

COMMUNICATON LETTER
APPROVAL PAGE

FIELD CORRECTIVE ACTION # 95

BUSINESS UNIT: CRITICAL CARE

PRODUCT DESCRIPTION: Vigileo (MHM1E), Vigilance II (VIG2E, VIG2) and
EV1000A, (EV1000A) monitors

SIGNATURES

Approved by: Michael Collins 
BU Quality Management Representative


6/6/2018
Date

Approved by: Joanna Develter 
BU, Regulatory VP

07-Jun-2018
Date

JAMES WHITESIDE
Approved by: ~~Tim Patz~~
~~BU Market~~

07 JUN 2018
Date

US MARKETING
 07 JUNE 2018



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URGENT PRODUCT CORRECTION- ACTION REQUIRED

Model Numbers: Power Cord for Vigileo (MHM1E), Vigilance II (VIG2E, VIG2) and EV1000A, (EV1000A) monitors

20 Jun 2018

<Customer #>

<Contact name or Dept.>

<Firm Name>

<Attention: RISK MANAGEMENT>

<CC: Chairman of Medical Board and Head of Department>

<Address>

<City/state/zip>

Dear Valued Customer:

As part of our strong commitment to quality, we are always monitoring our products throughout their life cycle to quickly identify and correct issues. We recently discovered an issue with a product and are initiating a voluntary correction.

Details on affected devices:

Vigileo, Vigilance II, MHM1E, and EV1000A monitors supplied with non-Edwards power cords.

Description of product:

These monitoring systems measure multiple hemodynamic parameters such as cardiac output (CO) both continuously (CCO) and intermittently (ICO), continuous oxygen saturation (SvO2, ScvO2) as well other parameters depending on which monitor is used. These hemodynamic parameters are to be used as an adjunct in patient assessment.

Description of the problem:

The power cord that was included with various Edwards monitors is not able to be used in Thailand, Philippines, Singapore, and Malaysia because the power cord pin type provided with original packaging is different from the pin type that is used in the local country. Therefore, in order to complete the installation of the monitor/equipment, a power cord with country specific pin was supplied from a non-Edwards approved source in order to run the monitor/equipment.

This issue poses no risk to patients.

Action to be taken by the user:

Replace the non-Edwards supplied power cord with new power cord(s) provided by Edwards Lifesciences enclosed with this Customer Letter and complete and return the Customer Acknowledgement form.

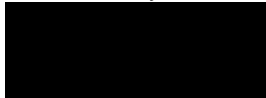


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At Edwards Lifesciences, we are committed to helping you advance the care and treatment of patients. This commitment extends to the products, service, education, and support we provide. We apologize for any inconvenience caused by this action and appreciate your attention in this matter.

If you have any questions please contact **Edwards Technical Support at +65 9658 4570.**

Sincerely,



Michael Collins
Vice President of Quality, Critical Care



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URGENT PRODUCT CORRECTION- ACTION REQUIRED
Model Numbers: Power Cord for Vigileo (MHM1E), Vigilance II
(VIG2E, VIG2) and EV1000A, (EV1000A) Monitors

CUSTOMER ACKNOWLEDGEMENT

<Customer #>

<Contact name or Dept.>

<Firm Name>

<Attention: RISK MANAGEMENT>

<CC: Chairman of Medical Board and Head of Department>

<Address>

<City/state/zip>

Our records show you currently have the following units with non-Edwards supplied power cords at your site:

Product Model Number	Serial Number	Number of Units with non-Edwards supplied cords

Please follow the instructions below to complete the correction process:

1. **Please check the box below to confirm you acknowledge receipt of this communication:**

☐

Yes. I acknowledge and understand the contents of this communication

2. Verify your inventory and replace the non-Edwards supplied power cords with the proper Edwards power cords provided with this Customer Acknowledgement form.
3. Discard the non-Edwards supplied power cords
4. Complete and sign the table below.
5. **Fax the completed form to Edwards Customer Service at +65 6883 6792.**

Name (Print):

Telephone Number:

Signature:

Date:

For any additional questions, please call Edwards Technical Support at +65 9658 4570.