



Edwards

**URGENT MEDICAL DEVICE RECALL –
ACTION REQUIRED**

Field Corrective Action #135

Product: DPT System

Model Numbers: PXAVMP3

Lot Numbers: 61547359

Aug 05, 2019

<Customer #>

<Contact name or Dept.>

<Firm Name>

<Attention: RISK MANAGEMENT>

cc: Chairman Medical Board and relevant Head of Departments

<Address>

<City/state/zip>

Dear Valued Customer:

As part of our strong commitment to quality, Edwards Lifesciences continuously monitors our products throughout their life cycle to quickly identify and correct any potential issues. We recently became aware of an issue with one lot of a Disposable Pressure Transducer System where customers are having difficulty priming the system. We request that you complete the attached Acknowledgement Form and return to Edwards Lifesciences per the instructions on the form. The product is being voluntarily recalled by Edwards Lifesciences.

Description and Indication of product being recalled:

The Edwards pressure monitoring kit with TruWave disposable pressure transducer is a sterile, single-use kit that monitors pressures when attached to pressure monitoring catheters. The disposable sterile cable interfaces exclusively with an Edwards cable that is specifically wired for the monitor being used. The TruWave disposable pressure transducer has a straight, flow-through design across the pressure sensor, and is available with or without the integral flush device.

The pressure monitoring kit with TruWave disposable pressure transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.

Description of the problem:

This non-conformance has to do with the inability to flush a Disposable Pressure Transducer System upon the initiation of priming. If this occurs, the clinician can obtain another DPT with minimal delay in set-up time. This occurs before use.



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If you have any questions, please contact Edwards Customer Service or Tech Support at +65 9658 4570, option 1.

Sincerely,



Sunita Das
Director | Quality Assurance
Edwards Lifesciences



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CUSTOMER ACKNOWLEDGEMENT

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<Firm Name>

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cc: Chairman Medical Board and relevant Head of Departments

<Address>

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Please follow all instructions below to complete the acknowledgement process.

Complete this acknowledgement form with the following information:

- Verify your inventory
- Complete all sections of the table below, indicate "0" if you have no product
- If you have unused product to return, call Customer Service or Tech Support at +65 9658 4570, option 1, to obtain a Returned Good Authorization (RGA) number.
- E-mail the completed form to Edwards Customer Service or Tech Support at +65 9658 4570 within 10 days from receipt of this notification

Model	Lot Number	PO#	Ship To Date	Quantity Shipped From EW	Number of units to be returned	RGA Number
PXAVMP3	61547359					

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

Please return this form via fax to Edwards Customer Service or Tech Support at +65 9658 4570.