



Edwards

**MEDICAL DEVICE RECALL
ACTION REQUIRED**

Field Corrective Action #135

Product: Disposable Pressure Transducer System

Model Numbers: PX3X3 (Affected model in Singapore)

Lot Numbers: 62013192 (Affected lots in Singapore)

6th Nov 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 became aware that some Disposable Pressure Transducer configurations had 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. You may contact Edwards Customer Service at + [REDACTED] (Karean Ng), [REDACTED] for a Return Goods Authorization (RGA) number to return identified inventory for a credit. Customer Service can assist you with placing a new order to replace this inventory, or you may place an order through EDI if that is more convenient.

Please note that there are other affected model numbers and/or lots affected globally, and you may contact and verify with product owner if in doubt.

Description and Indication of product being recalled:

The Edwards pressure monitoring kit with the TruWave disposable pressure transducer is a sterile, single-use kit that monitors pressures when attached to pressure monitoring catheters. The pressure transducer and disposable sterile tubing interface exclusively with an Edwards cable that is configured 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.



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Description of the problem:

This non-conformance is due to the inability to flush a Disposable Pressure Transducer System upon the initiation of priming. If this inability to flush occurs, the clinician can obtain another transducer kit with minimal delay in set-up time. This issue occurs during setup and before use.

If you have any questions, please contact respective Edwards Sales Representative or Customer Service at [REDACTED] (Karean Ng), [REDACTED].

Sincerely,

[REDACTED]

Sunita Das
Director | Quality Assurance
Edwards Lifesciences



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Product: DPT Pressure Monitoring System

Model Numbers: PX3X3 (Affected model in Singapore)

Lot Numbers: 62013192 (Affected lot in Singapore)

CUSTOMER ACKNOWLEDGEMENT

<Customer #>

<Firm Name>

<Attention: RISK MANAGEMENT>

cc: Chairman Medical Board and relevant Head of Departments

<Address>

<City/state/zip>

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 at [REDACTED] (Korean Ng), [REDACTED] to obtain a Returned Good Authorization (RGA) number.
- Complete and return the attached Acknowledgement Form within five (5) business days of receiving this notice to Edwards Sales Representative or Customer Service at + [REDACTED] Korean Ng), [REDACTED]

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

Name (Print): _____

Title/Dept. _____

Telephone Number: _____

Signature: _____

Date: _____