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Edwards Lifesciences
URGENT: MEDICAL DEVICE CORRECTION
ACTION REQUIRED

Field Corrective Action # 181
Product: TruWave Disposable Pressure Transducer,
FloTrac Sensors, Acumen IQ Sensors

UDI / Model Numbers: See Table 1
Lot Numbers: See Customer Acknowledgement Form

19 Oct 2023

<Customer #>

Attention: Risk Management

<Firm Name>

<Address/City/state/zip>

Attention: Risk Management Department

cc: Chairman Medical Board and relevant Head of Departments

Dear Valued Customers and Distributors:

Edwards Lifesciences is voluntarily notifying customers of an issue regarding certain lots of TruWave Disposable Pressure Transducers (DPTs), FloTrac Sensors, and Acumen IQ Sensors.

Intended Use:

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

The FloTrac Sensors and Acumen IQ Sensors are indicated for use in intravascular pressure monitoring. They are also indicated for the use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output.

Description of the Problem:

Edwards recently confirmed 53 customer complaints noting flushing difficulties during setup of the devices listed above. None of the complaints have resulted in serious injury or illness.

The investigation revealed a manufacturing issue causing a potential occlusion within certain devices.

Some devices were fully occluded and could not be flushed, while other devices were partially occluded causing slower flushing.

Risk to Health:

Flushing difficulties may cause a procedural delay. There is no anticipated patient harm due to the issue as it is detected prior to use when flushing the device, per the Instructions For Use (IFU).

The manufacturing issue was resolved, and newly manufactured devices are not impacted.



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Actions to be Taken:

- No product return is necessary.
- You may continue to use the product and follow the IFU for proper setup and flushing of your device.
- If you experience flushing difficulties, please use a new device.
- Verify your inventory on the attached customer acknowledgement form.
- Distribute this notice within your organization or to any organization where the potentially impacted product has been transferred.
- Please post a copy of this notice near and/or with affected devices.
- Complete and e-mail the customer acknowledgement form to Edwards Customer Service at CustomerService_MY@edwards.com, within 15 days from receipt of this notification.
- Contact Edwards Customer Service at +60 3 2289 3776 if you would like to return any of your devices or have further questions.

Actions to be Taken for Distributors:

In addition to the actions above, please forward this customer communication to any of your customers who have purchased the impacted product.

Transmission of the Product Correction Notice:

This notice needs to be passed on to all individuals within your organization who need to be aware of this correction. Please transfer this notice to other organizations if the impacted product has been transferred or distributed to other facilities.

Your assistance is appreciated and necessary to ensure that this notice is reviewed and understood. This Field Corrective Action has been communicated by Edwards to the applicable Regulatory authorities.

Sincerely,

Sunita Das
Sr. Dir, Quality



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Table 1

Product Family	Model Number	UDI
TruWave DPT	T001657A	07460691902046
	PXVP2272	07460691950184
	PXVP2284	07460691950177
	PXVP23X3AT3	07460691950443
	T494C00B	07460691950313
	T433803A	07460691926714
	T441T01C	07460691928848
	PX4X4	07460691950665
	PXMK1876	07460691953826
	PXMK1940	07460691955981
	PXVP2260	07460691950108
	PX260	07460691950191
	T005021M	07460691959538
	T100671M	07460691959491
	T001767A	07460691947306
	PXVP0550	07460691949911
	PXMK2321	07460691958784
	T005091M	07460691959552
	PX600F	07460691945555
	PXVFL10017	00690103210798
	T005089M	07460691959545
	T001691A	07460691947627
	PXMK2041	07460691951464
	PXMK2331	07460691959224
	PXVMP184	07460691955103
	PXAVMP3	07460691950085
	PXVMP160	07460691955080
	PX2X2	07460691950061
	T001691M	07460691959477
	T001709A	07460691947610
	T001660A	07460691902077
	PXVP2X2AT3	07460691950467
	PX284	07460691950214
	PXVMP3X32	00690103016802
	PXMK2043	07460691956230
	PXVPL0111	00690103200386
	PXVP0034	00690103197945
	PXMK2024	07460691958180
	PXVP1087	07460691957886
	PXVP1071	07460691955462
	PXVP23X3	07460691950092
T001658A	07460691902053	
PXMK0102	00690103199932	



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Product Family	Model Number	UDI
TruWave DPT	PX3X3284C	07460691950269
	PXVMP260	07460691950535
	PXVMP172	07460691955097
	T001744M	07460691959507
	T440B26B	07460691949553
	T530219D	07460691948259
	PXVP2284AT3	07460691950436
	T001760A	07460691947566
	PX212	07460691950221
	PXVK1099	07460691958753
	PX272	07460691950207
	T321573A	07460691910270
	PXVK0364	07460691954526
	PXAVMP	00690103011494
	PXVP0041	00690103197983
	PXVMP2X22	00690103016765
	T001765A	07460691947290
	T460241A	07460691949188
	PXVK0996	07460691955431
	PXMK9146	07460691954427
	T434501B	07460691956636
	PXVK0853	07460691957671
	PXVMP2X21	07460691950115
	T450545A	07460691931572
FloTrac Sensor	MHD8	00690103194609
	MHD85	00690103194616
	MHD6AZ5	00690103194746
	MHD8R5	07460691949744
	MHD8R	07460691949829
	MHD6AZ	00690103194722
	MHD6C502	00690103194760
	MHD6R5	07460691949737
	MHD8S	07460691949805
Acumen IQ Sensor	AIQS85	00690103200942
	AIQS6AZ	00690103201109
	AIQS6AZ5	00690103200980
	AIQS6	00690103201079
	AIQS65	00690103200935
	AIQS8	00690103201086
	AIQS6R5	00690103200959
	AIQS8R5	00690103201178
AIQS6R	00690103201093	



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**Product: TruWave Disposable Pressure Transducer,
FloTrac Sensors, Acumen IQ Sensors**

CUSTOMER ACKNOWLEDGEMENT FORM

<Customer #>

Attention: Risk Management

<Firm Name>

<Address/City/state/zip>

Attention: Risk Management Department

cc: Chairman Medical Board and relevant Head of Departments

Dear Customers and Distributors:

Please review and verify your inventory in the table below for your impacted devices.

- Provide all requested contact information below.
- E-mail the completed form to Edwards Customer Service at CustomerService_MY@edwards.com, within 15 days from receipt of this notification.
- Contact Edwards Customer Service at +60 3 2289 3776 for the RGA number if you would like to return any of your devices or have further questions. Please note, there may be a delay in receiving replacement products.

Model	Lot Number	PO Number	Order Date	Quantity Shipped From EW	Number of Units to be Returned	RGA

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