Edwards

URGENT MEDICAL DEVICE CORRECTION
ACTION REQUIRED
Field Corrective Action # 168

Products: FORE-SIGHT ELITE Tissue Oximeter Module

Model Numbers: HEMFSM10
Serial or Lot Numbers: Refer to Annex
UDI: 00690103208573

01 Mar 2022

<Customer #>
<Contact name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<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 a product correction related to the FORE-SIGHT ELITE Tissue Oximeter Module with the model number listed above. Edwards has received three (3) internal complaints related to this issue. There is no need to return any product. The impacted products are intended for monitoring absolute regional hemoglobin oxygen saturation (StO_2) of blood under the sensors.

Description of the problem:
The StO_2 values may be inaccurately low when using the FORE-SIGHT ELITE Tissue Oximeter Module (Model HEMFSM10) with the Fore-Sight Elite large sensor (FSESL) in certain somatic locations (arms and legs). While the StO_2 absolute values are impacted, the directional trend remains accurate, but may have a larger magnitude change.

Adult cerebral and flank/abdomen locations using the large sensor are not impacted. Measurements made during pediatric and pediatric neonatal monitoring with small and medium sensor sizes are not impacted.

Risk to Health:
Low StO_2 values may lead to unintended or inappropriate treatment. The low StO_2 values are noticeable upon start-up when using the large sensors. This will allow the clinician to assess the patient's clinical condition prior to performing any additional treatment. The system will alarm if the values are outside of the set physiological range.

Indications for use/Product description:
FORE-SIGHT ELITE Tissue Oximeter Module:
The noninvasive FORE-SIGHT ELITE tissue oximeter module is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the Sensors in individuals at risk for reduced-flow or no-flow ischemic states. The FORE-SIGHT ELITE tissue oximeter module is intended to allow for the display of StO_2 on the HemoSphere advanced monitor.

- When used with large sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with Medium Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for use on pediatric subjects ≥3 kg.
- When used with Small Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

Advice on action to be taken by user:
Customers are to refrain from using the large sensors on certain somatic locations (arms and legs). Cerebral and flank/abdomen locations for the large sensors are not impacted.

Instructions for customers:
- Review the customer letter for advice on how to use impacted product.
- Please follow the instructions included in the enclosed acknowledgement form to complete the acknowledgement process.
- Do not return any product.
- Distribute this notice within your organization or to any organization where the potentially impacted product has been transferred.
- Verify your inventory.
- E-mail the completed form to CustomerService_MY@edwards.com, within 15 days from receipt of this notification.

Advice on action to be taken by Distributor:
Please review this letter and complete the acknowledgement form. Return the acknowledgement form to CustomerService_MY@edwards.com within 15 days of receipt of this notification. Please forward this customer communication to any of your customers who have purchased the impacted Edwards product. If you still have product within your control, please do not distribute impacted product to any customers. You can call Edwards Customer Service for instructions for handling product still within your control.

Alternatively, you can provide Edwards with a list of your customers who have purchased the impacted product from you and Edwards will communicate directly with your customers to facilitate the correction and acknowledgement process. Please forward your customer list to CustomerService_MY@edwards.com. If you have any questions, please contact Edwards Customer Service at + 6 03 2289 3776.

Adverse Event Reporting in the US:
- Please contact the FDA's MedWatch Adverse Event reporting program either online, by regular mail, or by fax: Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form or submit by fax to 1-800-FDA-0178.

Transmission of the Product Correction:
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.

If you have questions, contact Edwards Customer Service at + 6 03 22893776.

Sincerely,

Sunita Das

Digitally signed by Sunita Das
DN: cn=Sunita Das, email=Sunita_Das@edwards.com
Reason: I am approving this document
Date: 2022.03.02 09:51:22 +05'30'

Sunita Das
Director I, Quality

Edwards

URGENT MEDICAL DEVICE CORRECTION
ACTION REQUIRED
Field Corrective Action # 168

Products: FORE-SIGHT ELITE Tissue Oximeter Module
Model Numbers: HEMFSM10
Serial or Lot Numbers: Refer to Annex
UDI: 00690103208573
CUSTOMER ACKNOWLEDGEMENT

<Customer #>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Attention: Risk Management Department
cc: Chairman Medical Board and relevant Head of Departments

Distributors:
Please complete the acknowledgement form and forward the Customer Letter to any of your customers who have purchased the impacted FORE-SIGHT ELITE Tissue Oximeter Module

Customers and Distributors:

- Review the customer letter for advice on how to use impacted product.
- Please follow the instructions included in the enclosed acknowledgement form to complete the acknowledgement process.
- Do not return any product.
- Distribute this notice within your organization or to any organization where the potentially impacted product has been transferred.
- Verify your inventory.
- E-mail the completed form to CustomerService_MY@edwards.com , within 15 days from receipt of this notification.

If you have any questions, contact Edwards Customer Service at + 6 03 22893776.

Model	Serial Number	Quantity Shipped From EW	Number of Units on Hand

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