URGENT FIELD SAFETY NOTICE

FCA # 168

Products: FORE-SIGHT ELITE Tissue Oximeter Module and FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor
Model Numbers: HEMFSM10 and 01-06-3000

Serial Numbers: See serial numbers in Acknowledgement Form
UDI Codes: 00690103208573 and 10609538630009

ACTION REQUIRED

<MM DD, YYYY>

<Customer #>
<Contact name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Dear Valued Customers and Distributors:

Edwards Lifesciences is voluntarily notifying customers of a product correction related to the FORE-SIGHT ELITE Tissue Oximeter Module and the FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor with the model numbers listed above. There is no need to return any product.

Details on affected devices:

The impacted products are intended for monitoring absolute regional hemoglobin oxygen saturation (StO_2) of blood under the sensors.

FORE-SIGHT ELITE Tissue Oximeter Module**:**

The non-invasive FORE-SIGHT ELITE Tissue Oximeter Module is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor 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 and is indicated for use as follows:

- 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 < 5 kg.

FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor**:**

The non-invasive FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced-flow or no-flow ischemic states and is indicated for use as follows:

- When used with Large Sensors, the FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with Medium Sensors, the FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor is indicated for use on pediatric subjects ≥ 3 kg.
- When used with Small Sensors, the FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor is indicated for cerebral use on pediatric subjects < 8 kg and non-cerebral use on pediatric subjects < 5 kg.

Description of the problem and indication to the user and distributor:

The StO_2 values may be inaccurately low when using either the FORE-SIGHT ELITE Tissue Oximeter Module (Model HEMFSM10) or the FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor (Model 01-06-3000) 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.

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.

Edwards has received three (3) internal complaints related to this issue.

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 Edwards Customer Service at XXX-XXX-XXX, within 15 days from receipt of this notification.

Edwards

Advice on action to be taken by Distributor**:**

Please review this letter and complete the acknowledgement form. Return the acknowledgement form to Edwards Customer Service at XXX-XXX-XXX 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 Tech Support for instructions for handling product still within your control.

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 Competent Authorities.

If you have questions, contact Edwards Tech Support at XXX-XXX-XXX

Sincerely,

L. Torres

Linnette Torres
Vice President of Quality, Critical Care

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ACKNOWLEDGEMENT FORM

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

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 and/or FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor.

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 Edwards Customer Service at XXX-XXX-XXX, within 15 days from receipt of this notification.

If you have any questions, contact Edwards Tech Support at XXX-XXX-XXX

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

Name (Print):	
Title/Dept.	

Telephone Number:	
Signature:	
Date:	