



## **UPDATE TO URGENT FIELD SAFETY NOTICE**

### **FCA # 168**

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

**Model Number:** HEMFSM10

**UDI:** 00690103208573

03/06/2023

#### **Dear Valued Customers and Distributors:**

A software update is now available to address Field Corrective Action (FCA) #168 issued March 08, 2022. This is the same issue previously communicated. There is no need to return any product.

FCA #168 was in response to inaccurate StO<sub>2</sub> value when using the FORE-SIGHT ELITE Tissue Oximeter Module (Model HEMFSM10) with the Fore-Sight large sensor (FSESL) in certain somatic locations (arms and legs).

The software for FORE-SIGHT StO<sub>2</sub> monitoring resides within the FORE-SIGHT ELITE Tissue Oximeter Module (Model HEMFSM10) which will need to be upgraded. The update can be performed by your Edwards representative.

As previously communicated, refrain from using the large sensors with FORE-SIGHT ELITE Tissue Oximeter Module (Model HEMFSM10) on certain somatic locations (arms and legs) until your software has been updated. Please note, the use of the large sensors may continue in unaffected locations.

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

This Update to the Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant Competent Authority.

Thank you for your ongoing patience as we rectified this issue and developed the software updates.

If you have questions or would like to schedule the software upgrades for your units, contact Edwards at [tech\\_support EU@edwards.com](mailto:tech_support_EU@edwards.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'A. Torres'.

Linnette Torres  
VP of Quality, Critical Care