URGENT FIELD SAFETY NOTICE

FCA #148

Product: HemoSphere Oximetry Cable

Model Number: HEMOXSC100

Serial Numbers: See table in Acknowledgement Form

MEDICAL DEVICE RECALL

<MM DD, YYYY>

<Customer #>
<Contact name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<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 HemoSphere oximetry cables have not met customer expectations.

Details on affected devices:
The HemoSphere oximetry cable is a multi-use device that connects to a compatible Edwards monitor on one end and any approved Edwards oximetry catheter on the other to continuously measure venous oxygen saturation by reflectance spectrophotometry. LEDs within the oximetry cable transmit light fiber optically to the distal end of the catheter. The amount of light absorbed, refracted, and reflected depends on the relative amounts of oxygenated and deoxygenated hemoglobin in the blood. This optical intensity data is gathered by the oximetry catheter, processed by the HemoSphere oximetry cable and displayed on a compatible monitoring platform.

Parameter output is mixed venous oxygen saturation (SvO2) or central venous oxygen saturation (ScvO2).

The HemoSphere advanced monitoring platform is intended to be used by qualified personnel or trained clinicians in a hospital setting. The HemoSphere advanced monitoring platform is intended for use with compatible Edwards oximetry and Swan-Ganz catheters.

Description of the problem and indication of product being recalled:

This issue involves HemoSphere oximetry cables that have operated at a temperature which may cause an Oximetry Cable Malfunction fault/error message and has the potential to stop producing Oximetry values. Although there have been complaints of the cable being warm to the touch, there have been no patient injuries noted to date. This non-conformance may cause a delay in the procedure while the product is exchanged.

Per investigation, the units were determined to be warmer than normal resulting in the cable shutting off due to internal safety checks, preventing the overheating from reaching a temperature that could cause injury/burn.

Edwards has designed a new hardware for the HemoSphere oximetry cable that is now available to address this issue.

The product with the previous hardware design is being voluntarily recalled. You may contact Edwards Technical Support at XXX-XXX-XXX for a Return Goods Authorization (RGA) number to return identified inventory for a credit. Technical Support can assist you with placing a new order to replace this inventory, or you may be contacted for an onsite visit to replace your inventory.

We request that you complete the attached Acknowledgement Form and return to Edwards Lifesciences per the instructions on the form.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions, please contact Edwards Technical Support at XXX-XXX-XXX, option 1.

Sincerely,

xxxxx
Vice President of Quality, Critical Care

This Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant competent authority.

Edwards

URGENT FIELD SAFETY NOTICE

FCA #148

Product: HemoSphere Oximetry Cable

Model Number: HEMOXSC100

Serial Numbers: See table below

CUSTOMER ACKNOWLEDGEMENT

<Customer #>
<Firm Name>
<Attention: RISK MANAGEMENT>
<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 do not have product
- If you have any product to return, call Edwards Technical Support at XXX-XXX-XXX, option 1, 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 Technical Support via fax at XXX-XXX-XXX

Model	Serial Number	Ship to Date	Quantity Shipped From EW	Number of units to be returned	RGA Number
HEMOXSC100					

Name (Print): _____

Title/Dept. _____

Telephone Number: _____

Signature: _____

Date: _____