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Product Notification - Action Required
ClearSight Heart Reference Sensor
Model Number: EVHRS
FCA-87

21 December 2017

CUSTOMER N° 46336326

AHCSC - ARABIAN HEALTHCARE
Attention: RISK MANAGEMENT
SUPPLY COMPANY - PO BOX 8772
OLAYAN PLAZA - ALHASA STREET
NEAR PEPSI COLA FACTORY
11492 RIYADH
Saudi Arabia

Dear Valued Customer:

As part of our strong commitment to quality, we are always monitoring our products throughout their life cycle to quickly identify and correct issues. We recently discovered an issue with a product and are initiating a voluntary recall.

Details on affected devices:

Heart Reference Sensor, consisting of model (EVHRS) and all serial numbers manufactured after December 31, 2015.

Description of product:

The Heart Reference Sensor also referred to as 'HRS', can be used with the EV1000 Clinical Platform NI to noninvasively measure blood pressure and key hemodynamic parameters using a ClearSight Finger Cuff wrapped around the finger. When using this method, the Heart Reference Sensor compensates for hydrostatic pressure changes due to a difference in height between the finger and heart.

Description of the problem:

The current product as well as the affiliated labeling contains an expiration date of two years. Through investigation and analysis of complaint data, we discovered that HRS units are susceptible to experiencing an "HRS Out of Range" error message in the EV1000 platform that are beyond six months from the date of manufacture. As a result, we have decided to change the expiration date to six months from the date of manufacture.

Additionally, this change will also require to replace the Operator's Manual of the EV1000 clinical platform and the Instructions for use (IFU) of the Heart Reference Sensor.

This issue poses no risk to patients as the EV1000 clinical platform will not allow the clinician to zero the device and initiate monitoring. This would create a pre-procedural delay while the troubleshooting process is completed. If the user does not encounter the "HRS Out of Range" message on the EV1000 clinical platform, the Heart Reference Sensor is functioning properly and patient monitoring is not adversely impacted. These products are used by highly trained clinicians, experienced in identifying and mitigating any



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hazards that arise during the use. In addition, these devices are typically used in Intensive Care Units or Operating Rooms, where the patients are closely monitored.

Action to be taken by the user:

- Please complete the attached acknowledgement form. For your convenience, we have pre-populated the form with the affected units you received. Please follow the instructions in the attached acknowledgment form to complete the recall process. This will assist us in determining the product replacement schedule to minimize any potential supply disruption
- As inventory of replacement Heart Reference Sensors is limited, an Edwards representative will contact the user to arrange for replacement
- If the user encounters the "HRS Out of Range" message on the EV1000 clinical platform, please contact Edwards Lifesciences Technical Support

At Edwards Lifesciences, we are committed to helping you advance the care and treatment of patients. This commitment extends to the products, service, education, and support we provide. We apologize for any inconvenience caused by this action and appreciate your attention in this matter.

This notice needs to be passed on to all those who need to be aware within your organization. Please transfer this notice to other organizations if the affected devices have been transferred to any another facilities.

Where applicable this product notification has been communicated by Edwards to the applicable authorities.

If you have any questions please contact **Edwards Customer Support at +971 4 299 1025**.

Sincerely,

Rogerio Feitor
Director Quality Systems EMEA



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CUSTOMER ACKNOWLEDGEMENT

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Please follow the instructions below to complete the recall process:

- Please check the box below to confirm you acknowledge receipt of this communication:**
 Yes. I acknowledge and understand the contents of this communication
- Verify your inventory
- Complete and sign the table below, indicate "0" if you have no inventory
- Fax the completed form to Edwards Customer Service at +971 4 299 1025**
- If you do not encounter the "HRS Out of Range" message on the EV1000 clinical platform, the Heart Reference Sensor is functioning properly and patient monitoring is not adversely impacted
- An Edwards representative will contact you to arrange your replacement and product return

If you encounter the "HRS Out of Range" message on the EV1000 clinical platform, please contact Edwards Lifesciences **Customer Support at +971 4 299 1025** and return your product to the following address:

Edwards Lifesciences – FCA87
2E 212 DAFZ
Dubai - UAE

Our records show you currently have the following Serial Numbers at your site:

Product Model Number	Serial Number	Order Number	Date Shipped from EW	Number of units to be returned	Number of units previously returned
EVHRS	600104013631	2S17052A / 20486187	20/03/2017		
EVHRS	600104013814	2S17052A / 20486187	20/03/2017		
EVHRS	600104013918	2S17052A / 20486187	20/03/2017		



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EVHRS	600104013917	2S17052A / 20486187	20/03/2017		
EVHRS	600104013916	2S17052A / 20486187	20/03/2017		

Name (Print):

Telephone Number:

Signature:

Date:

For any additional questions, please call Edwards **Customer Support at +971 4 299 1025.**