



Edwards

URGENT - PRODUCT RECALL
ClearSight Heart Reference Sensor
Model Number: EVHRS

December, 18 2017

CC: Chairman of Medical Board and Head of Department

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 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:



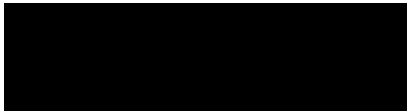
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- Please complete the attached acknowledgement form. For your convenience, we have pre-populated the form with the affected units you received. Please follow the instructions in the attached acknowledgement form to complete the recall process. This 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.

If you have any questions please contact **Edwards Technical Support at 1-800-822-9837 option 1** or Edwards Customer Service at +65 83381186 or +65 98192576

Sincerely,



Sunita Das
Sr. Manager Quality