

Edwards

5th Nov, 2019

Dear Valued Customer:

cc: Chairman Medical Board and relevant Head of Departments.

<EW Japan Address>

<Edward Lifesciences>

<Name of corporate president of Japan>

**SAFETY NOTIFICATION and Required action for
HemoSphere Advanced Monitor**

<Greeting>

As part of our strong commitment to quality, we continuously monitor our products throughout their life cycle to quickly identify and correct any potential issues.

Edwards recently received a complaint outside of Japan that the HemoSphere Advanced Monitor provided the incorrect PVRI (Pulmonary Vascular Resistance Index) value that was different from the expected value. After internal investigation, we have found out that the calculation formula of the PVRI built in the software of HemoSphere was not correct. PVRI is not a value that is continuously monitored based on patient information, but it is a value calculated based on the number entered by the user at the time. The calculation for the PVR (Pulmonary Vascular Resistance) is correct and as treatment decisions will not be determined by PVRI value alone, we believe there is low patient risk.

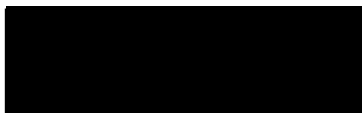
Although PVRI is just a supplementary value clinically, we have prepared a software to correct the calculation formula to have the correct PVRI value. Therefore, to correct the calculation formula with a software upgrade, we will take corrective action in the field.

Edwards has only received 1 report abroad and no such report has been received in Japan. No adverse event has been reported.

Request to customers

Please sign the "Customer Acknowledgement" form after confirming that the software upgrade to correct the calculation formula has been completed and provide to the sales representative. If you have any questions, please ask our sales representative.

Sincerely,



Sunita Das

Director | Quality Assurance

Edwards Lifesciences

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