URGENT - Field Safety Notice

Philips HaemoSphere R4.1
Calculation of the vascular resistances in the Philips HaemoSphere R4.1 evo, natal/ped in the special case of a shunt vitium.

Software update and IFU update.

Dear Customer,

A problem has been detected in the Philips HaemoSphere R4.1, Haemodynamic Catheter measuring station, that will lead to an incorrect calculation of the pulmonary resistance. This Field Safety Notice, 72200237 is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

If you need any further information or support concerning this issue, please contact your local Philips representative:

☎ **0800 80 3000**

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

H. de Jong
Sr. Director Q&R BIU: iXR

URGENT - Field Safety Notice

Philips HaemoSphere R4.1
Calculation of the vascular resistances in the Philips HaemoSphere R4.1 evo, natal/ped in the special case of a shunt vitium.

Software update and IFU update.

AFFECTED PRODUCTS	**System:** Philips HaemoSphere R4.1 **Productcode:** 722060
PROBLEM DESCRIPTION	The software of the Philips Haemo 4.1 calculates lesser circulation resistance (RP and RPI) from the difference between the mean pulmonary arterial and pulmonary venous pressure (or LA mean pressure) divided by the heart minute volume. This calculation method leads to a correct result, except in the special case of a shunt vitum. In this case, the calculation method that is used can lead to an incorrect calculation of pulmonary resistance. This contradicts the information in the user manual.
HAZARD INVOLVED	As a result, clinical users could incorrectly consider the calculated pulmonary resistance valid even in case of a shunt vitium. With the exclusive, uncritical evaluation of this parameter, therapeutic decisions based on it could be incorrect.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Philips HaemoSphere R4.1 systems as indicated in the “Affected Products” section mentioned above. A Unit Affected List (UAL) is provided to the local Philips representatives. Customers with affected systems will be contacted directly by the local Philips Organization.
ACTION TO BE TAKEN BY CUSTOMER / USER	The calculation for the vascular resistances may not be used in the presence of a shunt vitium.
ACTIONS PLANNED BY PHILIPS	A Mandatory Field Safety Corrective Action will be issued to solve this problem. This Field Change Order (FCO) will be identified as FCO72200237 and will be free of charge. • This FCO consists of a SoftWare update which, in cases where a shunt calculation was previously performed, ensures that the specific flows determined using the shunt calculation are used for the resistance calculation, so that in this case the vascular resistances can also be determined correctly even in the presence of a shunt vitium. • This FCO consists of an IFU update with a corrected text of the Chapter: “Vascular resistances”. The expected date of this FCO will be Q4, 2013
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: ☎ **0800 80 3000**