

Field Safety Notice

Philips Healthcare

PHILIPS

Ultrasound

-1/2-

FSN79500119/123

2008 July

URGENT - Medical Device Correction

HDI4000 Ultrasound Systems

Model HDI4000 Ultrasound System Estimated Fetal Weight Calculation

Dear Customer,

A problem has been detected in Philips ultrasound system model HDI4000 and, if it were to re-occur, could pose a risk for patients. This Medical Device Correction notification 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
- the action planned by Philips to correct the problem.

This document contains important information for the continued 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.

Philips ultrasound system model HDI4000 has a software defect that affects the display of Estimated Fetal Weight (EFW) Growth Percentile result values. All HDI4000 systems in distribution are affected.

Philips Ultrasound recently identified a software error in the method used to calculate and plot the Estimated Fetal Weight Growth Percentile result values when using the following EFW Growth tables: Brenner, Tokyo, Williams and Doubilet.

The fetal biometric measurement values used in the calculation of EFW are accurate. However, due to a software error, EFW growth percentile result values could be incorrectly calculated and reported to the user. When the actual EFW growth percentile is less than 50%, the system displays an erroneous value in the report. In certain cases the ultrasound system will report EFW growth percentile values between the 10th and 50th percentile, when the actual EFW growth percentile results value should be reported as less than the 10th percentile.

Philips Ultrasound is correcting the error. In the near future, your local field service representative will schedule a visit to your facility, free of charge, to upgrade the system software that corrects the error. In the interim, Philips recommends that you only use the Hadlock or Osaka growth tables to perform your EFW Growth Percentile calculations. You should adjust the settings on your system accordingly.

You are receiving this letter because our records indicate that your facility is affected by this situation.

Please forward this information to the appropriate individuals within your organization. If you need any further information or support concerning this issue, please contact your local Philips representative. This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,


Director, Quality & Regulatory

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AFFECTED PRODUCTS	HDI4000 Diagnostic Ultrasound System
PROBLEM DESCRIPTION	Philips ultrasound system model HDI4000 has a software defect that affects the display of Estimated Fetal Weight (EFW) Growth Percentile result values. All HDI4000 systems in distribution are affected.
HAZARD INVOLVED	EFW growth percentile is used to assist physicians in determining fetal health. Under certain circumstances a fetus whose EFW growth percentile is less than or equal to 10%, may be at risk for fetal distress or intrauterine growth retardation (IUGR). For these fetuses, if the EFW growth percentile is calculated using the Brenner, Tokyo, Williams and Doubilet EFW Growth tables, the system may incorrectly report a growth percentile greater than 10%.
HOW TO IDENTIFY AFFECTED PRODUCTS	All HDI4000 systems in distribution are affected. The system identification label for HDI4000 systems can be located on the rear of the unit in upper middle portion of the plastic housing. The Model is identified as HDI4000.
ACTION TO BE TAKEN BY CUSTOMER / USER	Until Philips provides the latest software revision, we recommend that you use only the Hadlock or the Osaka EFW Growth tables, which are not affected by the error. You should make the appropriate selections in the Analysis Setup menu on your system.
ACTIONS PLANNED BY PHILIPS	Philips is developing a new software revision to address this issue. Your local field service engineer will schedule a site visit to your facility to upgrade your system free of charge. The new software will be available in September 2008.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.