MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

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Model Number M1350B
Event Type Death
Event Description

The customer reported that the fetal monitor on a pregnant pt was giving fhr (fetal heart rate) readings on a pt who had already expired.

Manufacturer Narrative

The customer reported that the fetal monitor on a pregnant pt was giving fhr (fetal heart rate) readings on a pt who had already expired. Philips has explained that in certain cases, the nurse confuses the mhr (mother's heart rate) for fhr, which leads to monitoring of the mhr, while the fetus could be dead. The ifu for this device includes methods for verification of fetal viability when monitoring and for cross-channel verification to assure that the fetus is being monitored. Philips has no indication that these users utilized either of these approaches. The hospital tested the device and found it to be functioning as intended/specified. There is no indication that this issue could be difficult to detect. Additionally, the available information from this report does not support that this issue represents a systemic, design, or labeling problem. The product remains at the customer site. No further investigation or action is warranted.

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Brand Name	SERIES 50 XM FETAL/MATERNAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS Hewlett-Packard Str. 2 Boeblingen 7103 4 GERMANY 71034
Manufacturer Contact	Nancy Sayer 3000 Minuteman Road Andover , MA 01810 9786597429
MDR Report Key	1406028
Report Number	9610816-2009-00051
Device Sequence Number	1
Product Code	HGM[24]

Report Source Manufacturer
Source Type Health Professional,User facility,Company Representative
Reporter Occupation
Type of Report Initial
Report Date 06/17/2008
1 **Device Was Involved in the Event**
0 **PatientS WERE Involved in the Event:**
Date FDA Received 06/18/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator OTHER
Device MODEL Number M1350B
Was Device Available For Evaluation? Yes
Date Manufacturer Received 06/17/2008
Was Device Evaluated By Manufacturer? Yes
Date Device Manufactured 08/01/2005
Is The Device Single Use? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Reuse

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