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 user's report states that they were aware that the baby was not alive, but they were able to obtain hr sounds.

Manufacturer Narrative

(b)(4). The user's report states that they were aware that the baby was not alive, but they were able to obtain hr sounds. This is being reported only because use of the device was coincident with the stillbirth. There is no allegation or indication that use of the device was a factor in the stillbirth. The ability to obtain maternal hr using the us transducer is expected if the users move the transducer until they obtain hr sounds. The device labeling is clear that users are to verify fetal life before monitoring and that users should use the coincidence detection (ccv) feature to assure that the monitoring is not exclusively maternal.

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Brand Name	SERIES 50 XM FETAL/MATERNAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS 3000 Minuteman Road Andover MA 01810
Manufacturer Contact	Nancy Sayer 3000 Minuteman Road Andover , MA 01810 9786597429
MDR Report Key	1904069
Report Number	9610816-2010-00744
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 11/09/2010
1 **Device Was Involved in the Event**
1 **Patient Was Involved in the Event**
Date FDA Received 11/16/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator HEALTH PROFESSIONAL
Device MODEL Number M1350B
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 11/09/2010
Was Device Evaluated By Manufacturer? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Reuse

Patient TREATMENT DATA
Date Received: 11/16/2010 Patient Sequence Number: 1

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