MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

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Model Number M2702A
Event Type Death
Event Description

The customer reported that they detected a normal fetal heart rate (fhr) whereas the baby had previously died in utero.

Manufacturer Narrative

(b)(6): the customer reported that they detected a normal fetal heart rate (fhr) whereas the baby had previously died in utero. The report is fully consistent with failure to verify fetal life before beginning to monitor and with placement of the ultrasound transducer so that the mother was monitored. Per the instructions for use (ifu), fetal life should be verified before monitoring and the ccv (cross channel verification) functions should be used to alert clinicians if maternal heartrate (hr) is detected instead of fetal heartrate (fhr). Philips is in the process of obtaining additional info regarding this incident and the complaint is still under investigation. A final report will be submitted once the investigation is completed.

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Brand Name	AVALON FM20 FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS Hewlett-Packard Str. 2 Boeblingen 7103 4 GERMANY 71034
Manufacturer Contact	Nancy Sayer 3000 Minuteman Rd Andover , MA 01810 9786597429
MDR Report Key	1809185
Report Number	9610816-2010-00325
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	Health Professional,User facility,Company Representative

Reporter Occupation Other
Type of Report Initial
Report Date 08/09/2010
1 **Device Was Involved in the Event**
1 **Patient Was Involved in the Event**
Date FDA Received 08/13/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M2702A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 08/09/2010
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 04/01/2010
Is The Device Single Use? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Reuse

Patient TREATMENT DATA
Date Received: 08/13/2010 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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