MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

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Model Number M2703A
Event Date 06/24/2016
Event Type Death
Manufacturer Narrative

A follow-up report will be submitted once the investigation is complete.

Manufacturer Narrative

The provided trace has been evaluated by a philips rnd engineer and a philips clinician. Philips did not go on site to evaluate the device. Based on the evaluation, no product malfunction could be identified. Several warnings ¿check paper¿ and coincidence alarms have been printed on the trace indicating on one hand that the customer was not using philips paper and on the other hand that the device had detected a coincidence between the maternal pulse, obtained from the toco mp transducer and the fetal heart rate obtained from the ultrasound transducer. The available data supports that the device did not malfunction. The customer received a letter about the findings. Philips cannot determine if user error was a factor in the fetal demise, therefore any coincidences which the device alerted may have remained unrecognized. The device clearly indicated the detection of coincidence between the maternal pulse, obtained from the toco mp transducer and the fetal heart rate obtained from the ultrasound transducer.

Event Description

The customer reported the birth of a non-viable infant on (b)(6) 2016 at 21:18 after which the infant expired despite resuscitation efforts. The customer indicates that there was a discrepancy between the avalon fm30 cardiotocograph (ctg) data and the clinical outcome of the patient; the incident was not anticipated or expected based on the fetal monitor data.

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Brand Name AVALON FM30 FETAL MONITOR
Type of Device FETAL MONITOR
Manufacturer *(Section D)* PHILIPS MEDICAL SYSTEMS
Hewlett-Packard Str.2
Boeblingen 71034
GERMANY 71034
Manufacturer *(Section G)* PHILIPS MEDICAL SYSTEMS

	3000 Minuteman Road Andover MA 01810
Manufacturer Contact	Robert Corning 3000 Minuteman Road Andover , MA 01810 9786871501
MDR Report Key	5791986
Report Number	9610816-2016-00193
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	FOREIGN,USER FACILITY
Reporter Occupation	Health Professional
Type of Report	Initial,Followup
Report Date	07/08/2016
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/13/2016
Is This An Adverse Event Report?	Yes
Device Operator	Health Professional
Device MODEL Number	M2703A
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Event Location	No Information
Date Manufacturer Received	07/08/2016
Was Device Evaluated By Manufacturer?	Yes
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: 07/13/2016 Patient Sequence Number: 1

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