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 Type Death
Event Description

The customer reported that a ctg machine was recording a trace via a fetal scalp electrode on a fetus that had expired.

Manufacturer Narrative

The customer reported that a ctg machine was recording a trace via a fetal scalp electrode on a fetus that had expired. The available information supports that this was a user misunderstanding and not a malfunction. Philips is in the process of obtaining additional information concerning this event and the complaint is still under investigation. A final report will be submitted once the investigation is completed. (b) (4).

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Brand Name	AVALON FM30 FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS Hewlett-Packard Str. 2 Boeblingen 7103 4 GERMANY 71034
Manufacturer Contact	Greg Theokas 3000 Minuteman Road Andover , MA 01810 9786871501
MDR Report Key	1666075
Report Number	9610816-2010-00112
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 04/20/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 04/21/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M2703A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 04/16/2010
Was Device Evaluated By Manufacturer? No
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: 04/21/2010 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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