MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR

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Model Number M2705A
Event Date 01/14/2014
Event Type Death
Manufacturer Narrative
(b)(4). A follow up report will be submitted after philips obtains more information concerning this event.

Event Description
The customer reported that the fetal monitor traced the mother's heart treat as the fetus. The baby is decreased.

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Brand Name AVALON FM50 FETAL MONITOR
Manufacturer *(Section D)* PHILIPS MEDICAL SYSTEMS
3000 Minuteman Rd
Andover MA 01810
Manufacturer Contact Denyse Murphy
3000 Minuteman Road
Andover , MA 01810
9786597844
MDR Report Key 3640710
Report Number 9610816-2014-00029
Device Sequence Number 1
Product Code HGM[24]
Report Source Manufacturer
Source Type User facility,Company Representative
Reporter Occupation Other
Type of Report Initial
Report Date 01/14/2014
***1* Device Was Involved in the Event**

1 Patient Was Involved in the Event
Date FDA Received02/10/2014
Is This An Adverse Event Report?Yes
Is This A Product Problem Report?No
Device Operator Service Personnel
Device MODEL NumberM2705A
Was Device Available For Evaluation?Yes
Date Manufacturer Received01/14/2014
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: 02/10/2014 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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