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



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PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

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Model Number M2703A

Event Type Death

Event Description

The customer reported that an infant death occurred while being monitored on a philips device.

Manufacturer Narrative

(b)(4). The customer reported that an infant death occurred while being monitored on a philips device. Due to this request, it is considered that it was unclear for the customer how a fetal heart rate (fhr) could be measured on a fetus which is death for 2 days. The available information supports that the infant death occurred before the hospital began monitoring using the philips fetal monitor. The device documentation (instructions for use) stresses to confirm fetal life by independent means prior to initiating monitoring. Per the philips response center engineer (rce), there is no indication of fetal life. Per a philips registered nurse (rn), a review of the provided trace showed that no continuous measurement was used to gather the maternal pulse. Therefore, it was not possible for the device to compare the maternal heart rate (mhr) with the fhr to announce the user of a potential coincidence. Note that the device labeling instructs users to use coincidence detection (ccf) to assure that the measured heart rate is not the maternal heart rate. In addition, please note that the customer has provided 2 trace snippets from 2 different days ((b)(6) 2011) and two different devices for review. Philips will report this incident separately for both involved devices. Philips is in the process of obtaining additional information 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 NameAVALON FM30 FETAL MONITOR
Manufacturer (Section D)PHILIPS MEDICAL SYSTEMS
 3000 Minuteman Rd
 Andover MA 01810
Manufacturer ContactNancy Ataide
 3000 Minuteman Rd
 Andover , MA 01810
 9786597429
MDR Report Key1998690
Report Number9610816-2011-00090
Device Sequence Number1

Product CodeHGM²⁴**Report Source**Manufacturer**Source Type**Health Professional,User facility,Company Representative**Reporter Occupation**Other**Type of Report**Initial**Report Date**02/01/2011**1 Device Was Involved in the Event****1 Patient Was Involved in the Event****Date FDA Received**02/14/2011**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**02/01/2011**Was Device Evaluated By Manufacturer?**No**Date Device Manufactured**03/01/2008**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: 02/14/2011 Patient Sequence Number: 1****Links on this page:**

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