# 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** 02/09/2010
**Event Type** Death
**Event Description**

The customer reported that while monitoring a pt with periodic uterus contractions, using a series 50 monitor, the fetus was found in 3rd stage of maceration.

**Manufacturer Narrative**

The customer reported that while monitoring a pt with periodic uterus contractions, using a series 50 monitor, the fetus was found in the 3rd stage of maceration. The report of the fetus being macerated supports that the death was well before the initiation of monitoring and was unrelated to the monitoring. Based on the available info, the physician documented that the mistake made was that they did not measure the mother's heart rate (mhr) and there is no indication of a product malfunction. 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. (b) (4).

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|---|---|
| **Brand Name** | AVALON FM30 FETAL MONITOR |
| **Manufacturer *(Section D)*** | PHILIPS MEDICAL SYSTEMS<br>Hewlett-Packard Str.2<br>Boeblingen 7103 4<br>GERMANY 71034 |
| **Manufacturer Contact** | Nancy Sayer<br>3000 Minuteman Road<br>Andover , MA 01810<br>9786597429 |
| **MDR Report Key** | 1634970 |
| **Report Number** | 9610816-2010-00072 |
| **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** 03/10/2010
***1*** **Device Was Involved in the Event**
***1*** **Patient Was Involved in the Event**
**Date FDA Received** 03/16/2010
**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** 03/10/2010
**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: 03/16/2010 Patient Sequence Number: 1**

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