# MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR



## PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

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**Model Number** M2702A
**Event Type** Death
**Manufacturer Narrative**

(b)(4). The customer reported that a neonate was born in distress while being monitored by philips equipment and later died. The neonate was monitored with a fm20 fetal monitor and copy of tracing was provided. Customer has requested clarification about why the fhr was detected at certain times during monitoring and wants to know why alarms are not shown on recorded strips. Please note that these alarms are intended to show onscreen only and to not be printed and this does not represent any malfunction or failure to meet specifications. Note also that the tracing submitted shows no measurement of maternal heart rate, so coincidence detection would not be possible. 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.

**Event Description**

The customer reported that a neonate was born in distress while being monitored by philips equipment and later died.

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| | |
|---|---|
| **Brand Name** | AVALON FM20 FETAL MONITOR |
| **Manufacturer *(Section D)*** | PHILIPS MEDICAL SYSTEMS<br>3000 Minuteman Rd<br>Andover MA 01810 |
| **Manufacturer Contact** | Nancy Ataide<br>3000 Minuteman Road<br>Andover , MA 01810<br>9786597429 |
| **MDR Report Key** | 2423156 |
| **Report Number** | 9610816-2012-00019 |
| **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** 01/09/2012
***1*** **Device Was Involved in the Event**
***1*** **Patient Was Involved in the Event**
**Date FDA Received** 01/16/2012
**Is This An Adverse Event Report?** Yes
**Is This A Product Problem Report?** No
**Device Operator** Health Professional
**Device MODEL Number** M2702A
**Was Device Available For Evaluation?** Yes
**Is The Reporter A Health Professional?** Yes
**Date Manufacturer Received** 01/09/2012
**Was Device Evaluated By Manufacturer?** No
**Date Device Manufactured** 06/01/2008
**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: 01/16/2012 Patient Sequence Number: 1**

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