



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

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



[510\(k\)](#)⁷ | [DeNovo](#)⁸ | [Registration & Listing](#)⁹ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹ | [PMA](#)¹² | [HDE](#)¹³ | [Classification](#)¹⁴ | [Standards](#)¹⁵
[CFR Title 21](#)¹⁶ | [Radiation-Emitting Products](#)¹⁷ | [X-Ray Assembler](#)¹⁸ | [Medsun Reports](#)¹⁹ | [CLIA](#)²⁰ | [TPLC](#)²¹

PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

[Back to Search Results](#)

Model Number M2703A

Event Type Death

Manufacturer Narrative

(b)(4). The customer reported that a baby death occurred after being monitored by a philips device. This is being reported only because a philips device was in use on a baby who died. Based on the current, available information, the maternal heart rate (mhr) increased and coincided with the fetal heart rate (fhr), however, the fetal monitor showed/printed question marks. According to the statement from the head physician, the question marks were either ignored or not correctly interpreted due to human error. The baby suffocated during the birth. There is no indication of any malfunction of the (b)(6) avalon fm30. 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.

Event Description

The customer reported that a baby died after being monitored by a philips device.

[Search Alerts/Recalls](#)²²

[New Search](#) | [Submit an Adverse Event Report](#)²³

Brand NameAVALON FM30 FETAL MONITOR
Manufacturer (Section D)PHILIPS MEDICAL SYSTEMS
 3000 Minuteman Road
 Andover MA 01810
Manufacturer ContactNancy Ataide
 3000 Minuteman Road
 Andover , MA 01810
 9786597429
MDR Report Key2012314
Report Number9610816-2011-00116
Device Sequence Number1
Product Code[HGM](#)²⁴
Report SourceManufacturer
Source TypeHealth Professional,User facility,Company Representative

Reporter OccupationOther**Type of Report**Initial**Report Date**02/23/2011**1 Device Was Involved in the Event****1 Patient Was Involved in the Event****Date FDA Received**03/01/2011**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**02/23/2011**Was Device Evaluated By Manufacturer?**No**Date Device Manufactured**06/01/2009**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: 03/01/2011 Patient Sequence Number: 1**

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <https://www.fda.gov/MedicalDevices/default.htm>
5. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>

15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. <https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm>
23. <https://www.accessdata.fda.gov/scripts/medwatch/>
24. ../cfPCD/classification.cfm?start_search=&ProductCode=HGM

Page Last Updated: 01/31/2019

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)

[Accessibility](#) [Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Site Map](#) [Nondiscrimination](#) [Website Policies](#)



U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government](#) [For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency](#) [Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry](#) [Health Professionals](#) [FDA Archive](#)



U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <https://www.fda.gov/MedicalDevices/default.htm>

5. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>
22. <https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm>
23. <https://www.accessdata.fda.gov/scripts/medwatch/>
24. [../cfPCD/classification.cfm?start_search=&ProductCode=HGM](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=2012314&pc=HGM)