



[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 Date 03/14/2011

Event Type Death

Event Description

The customer reported that during the use of an avalon fm30 fetal monitor, there was a stillbirth.

Manufacturer Narrative

(b)(4). The customer reported that during the use of an avalon fm30 fetal monitor, there was a stillbirth. The mother had a heart frequency of 60-80 bpm and the fetal had a heart frequency of 120 to 140 bpm. The initial info indicated that the baby had been dead for several days before monitoring began. There is no indication that the clinicians verified fetal life before starting monitoring (as specified in the device labeling, instructions for use). The avalon fm30 fetal monitor is still in use at the site. This is being reported only because use of the device was coincident with the stillbirth. 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.

[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 Key2039045
Report Number9610816-2011-00163
Device Sequence Number1
Product Code[HGM](#)²⁴
Report SourceManufacturer

Source TypeHealth Professional,User facility,Company Representative
Reporter OccupationOther
Type of ReportInitial
Report Date03/21/2011

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received03/25/2011

Is This An Adverse Event Report?Yes

Is This A Product Problem Report?No

Device OperatorHealth Professional

Device MODEL NumberM2703A

Was Device Available For Evaluation?Yes

Is The Reporter A Health Professional?Yes

Date Manufacturer Received03/21/2011

Was Device Evaluated By Manufacturer?No

Date Device Manufactured01/01/2007

Is The Device Single Use?No

Is this a Reprocessed and Reused Single-Use Device?No

Type of Device UsageReuse

Patient TREATMENT DATA

Date Received: 03/25/2011 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=2039045&pc=HGM)