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



## PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

Back to Search Results

**Model Number** M2702A
**Event Date** 08/17/2015
**Event Type** Death
**Event Description**

The customer stated, "the doctor diagnosed a fetal movement using a m2702a avalon fm20 fetal monitor, but after an emergency surgery was made, they discovered, (b)(6) 2015, that the fetus was not alive".

**Manufacturer Narrative**

The m2702a avalon fm20 fetal monitor was tested onsite by the philips field service engineer. This evaluation has revealed no abnormalities and the device passed testing. The application team went on site and trained the customer. The device remains at the customer site for use. There is no indication of any systemic problem. The product instructions for use (ifu) is clear about independently verifying fetal life and fetal movement detection even if the fetus is not viable. No further investigation or action is warranted.

**Manufacturer Narrative**

A follow up report will be submitted once the investigation is complete. Contact office correction: (b)(4).

**Search Alerts/Recalls**[22]

New Search | Submit an Adverse Event Report[23]

| | |
|---|---|
| **Brand Name** | AVALON FM20 FETAL MONITOR |
| **Type of Device** | FETAL MONITOR |
| **Manufacturer *(Section D)*** | PHILIPS MEDICAL SYSTEMS<br>Hewlett-Packard Str.2<br>Böeblingen 71034<br>GERMANY 71034 |
| **Manufacturer Contact** | Wendy Chadbourne<br>3000 Minuteman Road<br>Andover , MA 01810 |
| **MDR Report Key** | 5021616 |
| **Report Number** | 9610816-2015-00176 |

**Device Sequence Number** 1
**Product Code** HGM[24]
**Report Source** Manufacturer
**Source Type** FOREIGN,USER FACILITY
**Reporter Occupation** Other
**Type of Report** Initial,Followup
**Report Date** 08/18/2015
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
**Date FDA Received** 08/21/2015
**Is This An Adverse Event Report?** Yes
**Device Operator** Health Professional
**Device MODEL Number** M2702A
**Was Device Available For Evaluation?** Yes
**Is The Reporter A Health Professional?** No
**Was the Report Sent to FDA?** No
**Event Location** No Information
**Date Manufacturer Received** 08/18/2015
**Was Device Evaluated By Manufacturer?** Yes
**Date Device Manufactured** 11/19/2014
**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: 08/21/2015 Patient Sequence Number: 1**

---

**Links on this page:**

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
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

FDA

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

USA.gov

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=fdamain

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