



[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 11/13/2017

Event Type Death

Event Description

The customer reported that the (b)(6) monitor did not warn clearly enough of a coincidence and the printout was misleading or unclear. A newborn died when the device was used for monitoring during delivery.

Manufacturer Narrative

A follow up report will be submitted once the investigation is complete.

Manufacturer Narrative

The customer stated that the warnings for a questionable fetal heart rate (fhr) were unclear to him, however, he suspected that the maternal heart rate (mhr) had been measured instead of the fhr. The customer complained that the monitor behavior is not clear and not sufficiently described in the instructions for use (ifu). According to the customer's problem description, the issue happened in the night from (b)(6) 2017. However, it was then determined based on the provided cardiocotograph (ctg) printout that the delivery took place in the night from (b)(6) 2017. The baby died on (b)(6) 2017. The service distributor was onsite to evaluate the reported issue and confirmed that no malfunction of the device was identified. Nevertheless, the biomedical engineer of the hospital sent the monitor to the philips factory for an additional evaluation. The returned device was checked by product support engineering (pse) who confirmed that the monitor successfully passed the final test. The logs of the monitor showed coincidence alarms at the time of the reported incident which were silenced manually by a user. By silencing alarms, the user acknowledges all active alarms by switching off audible alarm indicators. Pse confirmed that the device showed no malfunction and worked as specified. The customer was instructed about the intended functionality which is considered as all that is warranted for this issue. The product remains at the customer site and is still in use in the labor and delivery ward. Additionally, the available information from this report does not support that this failure represents a systemic, design, or labeling problem. No further investigation or action is warranted.

[Search Alerts/Recalls](#)²²

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

Brand NameAVALON FM30 FETAL MONITOR

Type of DeviceFETAL MONITOR

Manufacturer (Section D)PHILIPS MEDICAL SYSTEMS

Hewlett-Packard Str.2
Boeblingen 71034
GERMANY 71034

Manufacturer (Section G) PHILIPS MEDICAL SYSTEMS

3000 Minuteman Road
Andover MA 01810

Manufacturer Contact Betty Harris

Hewlett-Packard Str.2
Boeblingen 71034
GERMANY 71034

MDR Report Key 7063061**Report Number** 9610816-2017-00372**Device Sequence Number** 1**Product Code** HGM²⁴**Report Source** Manufacturer**Source Type** FOREIGN, HEALTH PROFESSIONAL, U**Reporter Occupation** Other**Type of Report** Initial**Report Date** 11/23/2017**1 Device Was Involved in the Event****1 Patient Was Involved in the Event****Date FDA Received** 11/28/2017**Is This An Adverse Event Report?** Yes**Is This A Product Problem Report?** Yes**Device Operator** Physician**Device MODEL Number** M2703A**Device Catalogue Number** 862199**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** 11/23/2017**Was Device Evaluated By Manufacturer?** Yes**Date Device Manufactured** 12/06/2016**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: 11/28/2017 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/tpic.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](..../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=7063061&pc=HGM)