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 04/23/2015
Event Type Death
Event Description

The customer stated that they were "monitoring with m2702a avalon fm20 fetal monitor s/n: (b)(4). Baby was born dead but the fetal monitor has recorded fetal heart rate (fhr) traces and fetal movements (fmp) although the fetus already was dead. User want to know how to identify it was mother's hr instead of fhr. There was fmp and contraction showed in the toco".

Manufacturer Narrative

Philips medical systems investigated the issue described above. On may 8, 2015, a philips field service engineer (fse) performed a functional test to verify the functionality of the avalon fm20 fetal monitor and determined that the device worked as specified. The provided trace recordings were reviewed by philips research & development department (r&d) and show: the heart rate baseline was around 120 bpm from 13:23 to 13:38 and from 14:16 to 16:08 with an increasing heart rate signal loss after 15:00. Movements were also recorded. From 18:01 to 18:48, only a toco transducer was applied (trace annotation ¿fhrx mode: no transducer¿). In addition a copy of the fetal monitor recording was provided, covering above mentioned time frames until 15:20. Based on the review of the provided traces and the additional information we received, it was determined that the philips device worked as specified. There is no indication that the clinicians verified fetal life before initiating fetal monitoring device labeling (instructions for use) instructs that ¿fetal monitoring technology available today is not always able to differentiate a fetal heart rate (fhr) signal source from a maternal heart rate (mhr) source in all situations ¿. This phenomenon is due to limitations of the technology and widely independent of the brand and model of the fetal monitor. In addition, an increased maternal pulse rate around and above 120 bpm is often seen with fetal demise. The maternal heart rate may be atypically high and therefore confused with that of a live fetus. Apparent fetal movement (fmp) may also be detected by the monitor but this may be a result of maternal movement causing the fetus to move within the amniotic fluid. Per philips (b)(4) and fse engineer, the m2702a avalon fm20 avalon fetal monitor with s/n: (b)(4) works as specified. No product malfunction. The m2702a avalon fm20 fetal monitor remains at the customer site. There is no indication of any malfunction of the m2702a avalon fm20 fetal monitor. The available information does not support that use of the device was contributory to the reported stillbirth. The cause of the stillbirth is unknown. Based on the review of the provided traces and the additional information we received, it was determined that our device worked as specified. Device labeling (instructions for use) instructs that ¿fetal monitoring technology available today is not always able to differentiate a fetal heart rate (fhr) signal source from a maternal heart rate (mhr) source in all situations ¿. Users should confirm fetal life by independent means before starting to use the fetal monitor. Since a mhr trace can exhibit features that are very similar to those of a fhr trace, users should not rely solely on trace pattern features to identify a fetal source. Also, fetal movement profile (fmp) annotations on a fetal trace alone may not always indicate that the fetus is alive. The body of a deceased fetus can move and cause the monitor to annotate. Maternal signal sources may be picked up when using the ultrasound transducer and could lead to misidentification when the mhr is higher than normal (especially when > 100 bpm).

Manufacturer Narrative

A follow up report will be submitted after philips obtains more information concerning this event.

Event Description

The customer stated that they were "monitoring with m2702a avalon fm20 fetal monitor s/n:(b)(4). Baby was born dead but the fetal monitor has recorded fetal heart rate (fhr) traces and fetal movements (fmp) although the fetus already was dead. User wants to know how to identify it was mother¿s hr instead of fhr. There was fmp and contraction showed in the toco. ".

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 Hewlett-Packard Str.2 Böeblingen 71034 GERMANY 71034
Manufacturer Contact	Denyse Murphy 3000 Minuteman Road Andover , MA 01810
MDR Report Key	4756179
Report Number	9610816-2015-00093
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	Foreign,User facility,FOREIGN,USER FACILITY
Reporter Occupation	Nurse
Type of Report	Initial,Followup
Report Date	04/29/2015
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/07/2015
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?	Yes
Was the Report Sent to FDA?	No
Event Location	No Information
Date Manufacturer Received	04/29/2015
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	07/11/2008
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: 05/07/2015 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

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