FDA

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

CDRH SuperSearch [6]

PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR   Back to Search Results

Model Number M2703A
Device Problem Incorrect Or Inadequate Test Results
Event Date 11/29/2016
Event Type Death
Manufacturer Narrative
A follow-up report will be submitted upon completion of the investigation.

Event Description
In this case the customer reported a patient incident with a deceased fetus where it is now in question why the monitor showed a fetal heart rate but the fetus was deceased.

Manufacturer Narrative
The patient is a (b)(6) year-old (b)(6) female, primigravida, presenting with a pregnancy at (b)(6) with a recently diagnosed fetal demise. The patient presented to the emergency room on (b)(6) 2016 in the morning complaining of decreased fetal movement. On workup ultrasound was done revealing fetal demise. Labs were, otherwise, unremarkable on her workup. Ultrasound that was done in the radiology department revealed the fetal demise. No cardia motion. The estimated age of the fetus was (b)(6). The placenta was anterior with no previa. Cervical length was 3. 1 cm. Afi was 16. 2. On the patient¿s presentation to the emergency room, there was a fetal heart rate trace taken. It showed a fetal heart rate between 150s to 170s with some unusual hyper variability. No apparent decelerations looking at the fetal heart rate tracing retrospectively. The maternal heart rate was measured with a spo2 transducer and was between 80s and 90s bpm. The provided data (log files and strips) have been evaluated in the factory by a philips clinician and the product support engineer. The log files showed no fatal errors. Evaluation of the provided strips identified that the fetal heart rate presented in the trace are duplicated maternal heart rates. From a technical point of view this is not a malfunction. The algorithm measuring the fetal heart rate is designed to detect pulsations from the fetal heart. In case the fetal is already demised, the algorithm will take the next best pulsating signal which is the maternal aorta. Due to the demised fetus swinging in the anionic fluid within in the ultrasound beam, the algorithm easily might double or half the detected heart rate. This is one limitation of the auto correlation algorithm. The auto correlation algorithm can display a doubled fetal or maternal heart rate if the duration of diastole and systole are similar to each other, and if the heart rate is below 120 bpm. Doubling, usually brief, is accompanied by an abrupt switch of the trace to double the baseline value. In addition the maternal heart rate may simulate a normal fetal heart rate pattern (i. E. , it may mask a fhr deceleration or fetal demise). It was found that the fetal life was not confirmed before starting patient monitoring as it is strongly recommend by philips. 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 fetal body movements. This is what the customer has seen in this case on the strips. There had been movement annotations even when the fetus was already deceased. The customer has not confirmed the fetal life before starting with patient monitoring. In case the fetus is already deceased when doing fetal monitoring the device might misinterpret the maternal heart rate obtained from the aorta as fetal heart rate. Due to the fact that deceased fetus is swimming in the anionic fluid in front of the aorta, these movements might be misinterpreted as fetal movement of a

well being fetus. Thus this case falls into a usage of outside normal and expected. The results of the event investigation and device evaluation have been provided to the customer in a customer letter. There was no malfunction of the device. The device remains at the customer site. No part failed.

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Brand Name	AVALON FM30 FETAL MONITOR
Type of Device	FETAL 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	Robert Corning
	Hewlett-Packard Str.2
	Boeblingen 71034
	GERMANY 71034
MDR Report Key	6171431
Report Number	9610816-2016-00314
Device Sequence Number	0
Product Code	HGM[24]
Report Source	Manufacturer
Reporter Occupation	Other
Type of Report	Followup
Report Date	11/29/2016
2 **DeviceS WERE Involved in the Event:**	1 2
1 **Patient Was Involved in the Event**	
Date FDA Received	12/13/2016
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?	No
Was the Report Sent to FDA?	No
Event Location	No Information
Date Manufacturer Received	11/29/2016
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	06/12/2015
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: 12/13/2016 Patient Sequence Number: 1

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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

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