MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS ULTRASOUND TRANSDUCER FOR USE WITH FM20/FM30 AVALON

[6]

PHILIPS MEDICAL SYSTEMS ULTRASOUND TRANSDUCER FOR USE WITH FM20/FM30 AVALON

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Model Number M2736A
Event Date 01/24/2012
Event Type Death
Manufacturer Narrative

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

Event Description

The customer sent an email query regarding a field action in 2009 for philips avalon fetal monitors. This was in relation to a case regarding a baby who died in (b)(6) hospital in 2012. A newborn died when the device was used for monitoring during delivery at (b)(6) 2012. The incident took place in the hospital delivery room.

Manufacturer Narrative

A baby died on (b)(6) 2012. The incident was not reported to philips at that time. The investigation determined that the customer requested assistance to clarify questions related to the field safety notice from 2009 concerning the ultrasound (us) transducer signal (i. E. Device detecting the fetal heart rate (fhr)). This complaint is registered on the us transducer as the doppler echoes are processed by the mainboard within the ultrasound transducer by an auto-correlation algorithm to determine fetal heart rate (fhr). The signal processing of the fhr is done by the firmware (software) on the transducer mainboard. The fhr is only reported on the monitor¿s numeric display and on the recorded trace. The full traces of the incident have been provided by the (b)(4) to philips for an evaluation by product support engineering (pse) and a clinician. Pse stated that the traces show that the customer used multiple devices during that patient monitoring episode. A philips physician and an external midwife assessed the traces and concluded the following: the trace shows fetal distress starting at 06:32 am. From that moment onwards, the fhr trace rarely shows signals from the fetus, and is instead almost exclusively showing a maternal signal. This phenomenon is well-known and inherent to the fetal monitor¿s ultrasound technology. Therefore, the fetal monitor is designed to compare a known maternal signal (e. G. Pulse measured by an spo2 finger sensor) with the ultrasound signal. This coincidence analysis is continuously done by the monitor and alerts the user in case of a coincidence. Here, the coincidence analysis was only intermittently possible because the maternal spo2 probe was not used continuously after epidural anesthesia was started. However, during those periods when the spo2 sensor was applied to the mother, the fetal monitor issued multiple coincidence alerts consistent with its design and labeling. The strips provided to philips show no indication of device malfunction. The investigation reveals that there is no relation between the death on (b)(6) 2012 and the field actions from 2009. The traces provided to philips show no indication of a device malfunction. The products remain at the customer site. The provided information shows that all avalon devices involved in the incident had the latest firmware on (b)(6) 2012. This complaint does not represent a product/part failure. No further investigation or action is warranted.

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Brand Name	ULTRASOUND TRANSDUCER FOR USE WITH FM20/FM30 AVALON
Type of Device	ULTRASOUND TRANSDUCER
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	7233465
Report Number	9610816-2018-00035
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	FOREIGN,HEALTH PROFESSIONAL,U
Reporter Occupation	
Type of Report	Initial
Report Date	01/24/2018
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/01/2018
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	Yes
Device Operator	HEALTH PROFESSIONAL
Device MODEL Number	M2736A
Device LOT Number	UNKNOWN
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	01/24/2018
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	12/05/2007
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: 02/01/2018 Patient Sequence Number: 1

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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

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
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