MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR PERINATAL MONITORING SYSTEM

PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR PERINATAL MONITORING SYSTEM

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Model Number M2705A
Device Problem Incorrect, Inadequate or Imprecise Result or Readings
Event Date 02/14/2018
Event Type Death
Event Description

The customer reported a patient monitoring issue. The customer reported an incident with ¿undesirable results¿. The device was used for monitoring at the time of the alleged malfunction. An incident with ¿undesirable results¿ was reported. The customer did not provide any patient information, although the customer service manager tried to obtain further patient details. The patient died.

Manufacturer Narrative

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

Event Description

The customer reported a patient monitoring issue. The customer reported an incident with ¿undesirable results¿. The device was used for monitoring at the time of the alleged malfunction. An incident with ¿undesirable results¿ was reported. The customer did not provide any patient information, although the customer service manager tried to obtain further patient details.

Manufacturer Narrative

The actual monitor used in the incident was checked by a field service engineer (fse) onsite. The device successfully passed the performance verification and electrical safety tests. No issue with the device was found by the fse. The provided trace of the incident was evaluated by product support engineering (pse). The fetal heart rate (fhr) was derived from a cableless (cl) ultrasound (us) transducer. From a technical viewpoint, the derivation of the us signal was excellent, although at around 20:24, the us transducer did not record a signal, likely due to bad positioning of the transducer. At 20:28, the spo2 sensor was removed and the maternal pulse was derived by the cl toco mp transducer. This signal was lost intermittently. From 20:31 to 20:32, the trace shows movement artifacts. Between 20:32 to 20:39, there is no sufficient signal from the mother to allow coincidence detection. A reliable second pulse or heart rate source is required to perform the cross channel verification. From 20:39 onwards, the pulse was again derived by a spo2 sensor. The device issued coincidence alerts at 20:19, 20:22, 20:28, and 20:30 as intended by design. No technical malfunction was observed by pse. The trace was also clinically assessed by a philips physician and an external advisory midwife. They observed that in general the trace shows no accelerations and oscillations with limited undulations. In combination with the decelerations, this pattern presents a suspicious trace. The trace shows deceleration with consecutive loss of fhr baseline. At 20:35, the us transducer probably recorded the maternal pulse source instead of the fetal heart rate. In those cases, the maternal pulse will be shown in fhr trace on the print out. However, because between 20:30 and 20:39, the maternal pulse trace was being lost intermittently, there was not any second pulse or heart rate source at that time; therefore, a cross channel verification could not be performed. At 20:39, it

appears that the us transducer switched back to the fetus. At 20:43, a fetal deceleration can be seen. The trace for the fetal signal ended at 20:45; possibly the transducer was removed from the mother¿s belly. The maternal pulse continued to be measured by the spo2 sensor until 21:00. The complete trace ended at approx. 20:57. A comprehensive trace analysis was not possible in this case as it requires additional data, such as therapy provided, patient history, etc. , which was not available in this case. The device worked as designed. No malfunction could be identified based on the provided information. The device remains at the customer site. The customer was informed via customer letter abut the outcome of the investigation. No further investigation or action is warranted.

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Brand Name	AVALON FM50 FETAL MONITOR
Type of Device	PERINATAL MONITORING SYSTEM
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	7376854
Report Number	9610816-2018-00089
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	USER FACILITY
Reporter Occupation	Other
Type of Report	Initial
Report Date	03/02/2018
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	03/28/2018
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device MODEL Number	M2705A
Device Catalogue Number	865071
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	03/02/2018

Was Device Evaluated By Manufacturer? Yes
Date Device Manufactured 10/21/2016
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: 03/28/2018 Patient Sequence Number: 1

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