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
Event Date 11/20/2017
Event Type Death
Manufacturer Narrative

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

Event Description

The customer called for application support to pull data from a monitor to see if alarms were visible and acknowledged. The customer reported that they had an adverse outcome where there was a concern with regard to heart rate coincidence between the fetal and the maternal heart rate. The device was used for monitoring at the time of the alleged malfunction. The customer stated that there was a delivery with an adverse outcome. No further details about the adverse event were made available by the customer.

Manufacturer Narrative

The issue was evaluated by the clinical specialist (cs) who checked whether the monitor's alarm configuration was set up as discussed with the customer during installation. The cs confirmed that all alarms were enabled correctly and the alarm pause mode was disabled. The cs stated that the trace of the particular adverse event showed question marks indicating the coincidence alarms (as intended when there is a coincidence between the measurements of fetal and maternal heart rate). Despite requested by the cs, the customer did not want to provide the trace for further evaluation by philips. Hence, no further investigation was possible. The cs confirmed that the alarm configuration was set correctly and that the trace of the particular adverse event showed question marks indicating the coincidence alarms. The fse performed a functional check of the monitor at the customer site and confirmed that the monitor worked as specified during testing. The product remains at the customer site. The device worked as intended and no malfunction of the device occurred. The alarm configuration was set correctly and the trace of the particular adverse event showed question marks indicating the coincidence alarms. No further investigation or action is warranted.

Event Description

The customer called for application support to pull data from a monitor to see if alarms were visible and acknowledged. The customer reported that they had an adverse outcome where there was a concern with regard to heart rate coincidence between the fetal and the maternal heart rate. The customer reported that the newborn required extensive resuscitation and later died. No further details about the adverse event (e. G. Patient data) were made available by the customer.

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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 7063811
Report Number 9610816-2017-00373
Device Sequence Number 1
Product Code HGM[24]
Report Source Manufacturer
Source Type FOREIGN,USER FACILITY
Reporter Occupation Other
Type of Report Initial
Report Date 11/20/2017
***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 Health Professional
Device MODEL Number M2705A
Device LOT Number TBD
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 11/20/2017
Was Device Evaluated By Manufacturer? Yes
Date Device Manufactured 09/15/2017
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

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22. https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
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