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

[6]

PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR PERINATAL MONITORING SYSTEM

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Model Number M2705A
Event Date 09/16/2015
Event Type Death

Manufacturer Narrative

The philips clinical consultant and philips ob monitoring solution specialist had an onsite visit on (b)(4) 2015. Addressing the issues of reading mom vs baby on the strips and addressing protocol on monitoring both patients and distinguishing mom¿s hr by checking the radial pulse to confirm and compare to the hr on the strip. The philips clinical consultant and philips ob monitoring solution specialist onsite reviewed the monitors with the staff. No trouble was found. The philips clinical consultant also reinforced training with the avalon fm50 and transducer station. The philips clinical consultant also discussed using the spo2 to get a pulse if the maternal pulse is lost during a contraction or end stage labor. Over all there was no problem with the philips monitoring system identified. The customer was receptive, open with their discussion and feedback. The m2705a avalon fm50 fetal monitor s/n: (b)(4) was tested onsite by the philips clinical consultant and the customer. This evaluation has revealed no abnormalities and the device passed. Additional training about the ifu content was provided to resolve the use issues. The device remains at the customer site for use. No further investigation or action is warranted.

Manufacturer Narrative

(b)(4). A follow up report will be submitted once the investigation is complete.

Event Description

The customer submitted a pimr and stated there was a misidentification of maternal heart rate as fetal, and the fetus died.

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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
Böeblingen 71034
GERMANY 71034
Manufacturer Contact Wendy Chadbourne

3000 Minuteman Road
Andover , MA 01810

MDR Report Key 5155541
Report Number 9610816-2015-00246
Device Sequence Number 1
Product Code HGM[24]
Report Source Manufacturer
Source Type USER FACILITY
Reporter Occupation Other
Type of Report Initial,Followup
Report Date 09/17/2015
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 10/16/2015
Is This An Adverse Event Report? Yes
Device Operator Health Professional
Device MODEL Number M2705A
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 09/17/2015
Was Device Evaluated By Manufacturer? Yes
Date Device Manufactured 03/27/2014
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: 10/16/2015 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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