MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

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Model Number M1350C
Event Type Death
Manufacturer Narrative

(b)(4). The customer reported that an infant death occurred while being monitored on a philips device. Due to this request, it is considered that it was unclear for the customer how a fetal heart rate (fhr) could be measured on a fetus which is dead for 2 days. The available information supports that the infant death occurred before the hospital began monitoring using the philips fetal monitor. The device documentation (instructions for use) stresses to confirm fetal life by independent means prior to initiating monitoring. Per the philips response center engineer (rce), there is no indication of fetal life. Per a philips registered nurse (rn), a review of the provided trace showed that no continuous measurement was used to gather the maternal pulse. Therefore, it was not possible for the device to compare the maternal heart rate (mhr) with the fhr to announce the user of a potential coincidence. Note that the device labeling instructs users to use coincidence detection (ccf) to assure that the measured heart rate is not the maternal heart rate. In addition, please note that the customer has provided 2 trace snippets from 2 different days ((b)(6) 2011), and two different devices for review. Philips will report this incident separately for both involved devices. Philips is in the process of obtaining additional information regarding this incident and the complaint is still under investigation. A final report will be submitted once the investigation is completed.

Event Description

The customer reported that an infant death occurred while being monitored on a philips device.

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Brand Name	SERIES 50 XM FETAL/MATERNAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS 3000 Minuteman Road Andover MA 01810
Manufacturer Contact	Nancy Ataide 3000 Minuteman Road Andover , MA 01810 9786597429
MDR Report Key	1999792
Report Number	9610816-2011-00091
Device Sequence Number	1

Product Code HGM[24]
Report Source Manufacturer
Source Type Health Professional,User facility,Company Representative
Reporter Occupation
Type of Report Initial
Report Date 02/01/2011
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 02/11/2011
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator HEALTH PROFESSIONAL
Device MODEL Number M1350C
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 02/01/2011
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 03/01/2008
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: 02/11/2011 Patient Sequence Number: 1

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Page Last Updated: 03/31/2019

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